

**UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

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IN RE: McNEIL CONSUMER	:	
HEALTHCARE, ET AL., MARKETING	:	
AND SALES PRACTICES LITIGATION	:	MDL NO. 2190
	:	
APPLIES TO: ALL ACTIONS	:	
	:	

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**PLAINTIFFS' OMNIBUS OPPOSITION TO DEFENDANTS' MOTIONS TO DISMISS**

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## TABLE OF CONTENTS

<b>TABLE OF AUTHORITIES .....</b>	<b>iv-xi</b>
<b>I. INTRODUCTION .....</b>	<b>1</b>
<b>II. SUMMARY OF FACTS .....</b>	<b>6</b>
<b>III. ARGUMENT .....</b>	<b>12</b>
<b>A. Standards for Motions to Dismiss. ....</b>	<b>12</b>
<b>B. Plaintiffs Have Standing To Sue the Individual, J&amp;J and Contractor Defendants. ....</b>	<b>14</b>
1. Plaintiffs’ Allegations Show that They Have Suffered Actual Injury in Fact. ....	15
2. Plaintiffs Claimed Injuries that Have Been Caused By the Conduct of the Contractor Defendants. ....	19
<b>C. Plaintiffs’ Amended Complaint Satisfies the Pleadings Standards of Rule 8 and, Where Applicable, Rule 9(b). ....</b>	<b>23</b>
1. The Bulk of Plaintiffs’ Causes of Action Do Not Sound in Fraud, Therefore Making the Particularity Requirement of Fed.R.Civ.P. 9(b) Inapplicable. ....	24
2. Plaintiffs’ Allegations State Claims for Relief Under the <i>Twombly</i> Standard. ....	26
<b>D. Plaintiffs’ Allege Sufficient Claims Under the Applicable Pleading Standards. ....</b>	<b>28</b>
1. Plaintiffs’ Allegations of Actual Injury Under the Relevant Consumer Protection Statutes of Their Home States Is Sufficient. ....	30
2. The Standards for Claims Under Other Stats’ Consumer Fraud Laws Have Been Met. ....	31
3. Plaintiffs Have Adequately Pled Their Federal RICO Claims. ....	31
a. Plaintiffs Allege Actual Injury Under RICO .....	32
b. Plaintiffs Have Satisfied RICO’s Pleading Requirements. ....	33

i.	Plaintiffs Have Alleged a Viable RICO Enterprise. . .	33
ii.	Plaintiffs Have Alleged that the Defendants “Conducted and Participated” in Enterprise Affairs. . . . .	37
iii.	Plaintiffs Have Alleged that the Defendants Participated in an Enterprise “Through a Pattern of Racketeering Activity”. . . . .	38
(1)	Plaintiffs Have Alleged Two Predicate Acts. . .	38
(2)	Plaintiffs Have Met the Continuity Requirement. . . . .	40
(3)	Plaintiffs’ Allegations Meet the Distinctiveness Requirement. . . . .	42
4.	Plaintiffs’ Claims for Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose are Adequately Pled Under the Laws of Their Home States. . . . .	44
5.	Plaintiffs’ Federal Magnuson-Moss Warranty Act Claims are Adequately Pled. . . . .	55
a.	Plaintiffs State a Claim for Breach of Implied Warranty. . .	55
b.	Plaintiffs Satisfy the MMWA’s Jurisdictional Requirements.	56
c.	Plaintiffs Allege a Breach of Express Warranty. . . . .	56
d.	Plaintiffs Satisfy All Notice Requirements. . . . .	57
6.	Plaintiffs Have Adequately Pled a Negligence Claim against Defendants. . . . .	58
a.	Plaintiffs’ Claims are not Completely Barred by the “Economic Loss Rule.” . . . .	60
7.	Plaintiffs’ Claims of Negligent Misrepresentation and Fraud are Adequately Pled Under the Laws of the Applicable States. . . . .	62
a.	Plaintiffs Have Adequately Pled Actual Injury Proximately Caused by the Defendants. . . . .	62
b.	Plaintiffs’ Negligent Misrepresentation Claims Are Adequately Pled Under the Laws of Their Home States. . . . .	62

<b>8. Plaintiffs' Claims of Conspiracy, Concert of Action and Aiding and Abetting Are Adequately Pled Under the Laws of Their Home States. ....</b>	<b>63</b>
<b>9. Plaintiffs' Claims for Unjust Enrichment are Adequately Pled. ....</b>	<b>65</b>
<b>10. Plaintiffs' Request for Declaratory Relief is Valid. ....</b>	<b>67</b>
<b>IV. CONCLUSION. ....</b>	<b>69</b>

## **TABLE OF AUTHORITIES**

<b>CASES</b>	<b>Page(s)</b>
<b>FEDERAL CASES</b>	
<i>AFA Corp. v. Phoenix Closures Inc.</i> , 501 F. Supp. 224 (N.D. Ill. Nov. 6, 1980).....	30,52
<i>American Federation of State County and Municipal Employees v. Ortho-McNeil-Janssen</i> , No. 08-cv-5904, 2010 WL 891150 (E.D.Pa. March 11, 2010).....	18
<i>Ashcroft v. Iqbal</i> , 129 S.Ct. 1937 (2009).....	<i>passim</i>
<i>Assoc. Gen. Contractors v. Cal. State Council of Carpenters</i> , 459 U.S. 519 (1983).....	12
<i>Atiyeh v. National Fire Ins. Co. of Hartford</i> , 742 F.Supp.2d 591, 596 (E.D.Pa. Sept. 27,2010).....	13
<i>Baker v. Fam. Credit Counseling Corp.</i> , 440 F.Supp.2d 392 (E.D.Pa. July 28, 2006)....	38
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	<i>passim</i>
<i>Bennett v. Spear</i> , 520 U.S. 154 (1997).....	22
<i>Bowman v. Wilson</i> , 672 F.2d 1145 (3d Cir.1982).....	15
<i>Boyle v. U.S.</i> , 129 S. Ct. 2237 (2009).....	<i>passim</i>
<i>Brantner v. Black &amp; Decker Mfg. Co.</i> , 831 F.Supp. 460 (W.D.Pa. Aug. 26, 1993).....	59
<i>Briehl v. Gen Motor Corps.</i> , 172 F.3d 623 (8 <sup>th</sup> Cir.1999).....	18
<i>Brittingham v. Mobil Corp.</i> , 943 F.2d 297 (3d Cir.1991).....	42
<i>Buck v. Hampton Twp. Sch. Dist.</i> , 453 F.3d 256, 260 (3d Cir.2006).....	14, 20
<i>Carbontek Trading Co., Ltd. v. Phibro Energy, Inc.</i> , 910 F.2d 302 (5 <sup>th</sup> Cir.1990).....	51
<i>Cedric Kushner Promotions, Ltd. v. King</i> , 533 U.S. 158 (2001).....	43
<i>Chavis v. Fidelity Warranty Svcs.</i> , 415 F.Supp.2d 620 (D.S.C. Feb. 13, 2006).....	56
<i>Clark v. Conahan</i> , 737 F.Supp.2d 239 (M.D.Pa. Aug. 25, 2010).....	29,30,37,38
<i>Clark v. McDonald's Corp.</i> , 213 F.R.D. 198 (D.N.J. March 3, 2003).....	31

<i>Consolidated Data Terminals v. Applied Digital Data Sys. Inc.</i> , 708 F.2d 385 (9th Cir. 1983).....	29,51
<i>Custom Automated Machinery v. Penda Corp.</i> , 537 F. Supp. 77 (N.D. Ill. Jan. 20, 1982).....	29
<i>Danvers Motor Co., Inc. v. Ford Motor Co.</i> , 432 F.3d 286 (3d Cir.2005).....	15
<i>DiLeo v. Ernst &amp; Young</i> , 901 F.2d 624 (7th Cir.1990).....	24
<i>Dongelewicz v. PNC Bank Nat'l. Ass'n.</i> , 104 Fed.Appx. 811 (3d Cir.2004)	
<i>Earle v. Benoit</i> , 850 F.2d 836, 844 (1st Cir.1988).....	64
<i>Emcore Corp. v. PricewaterhouseCoopers, LLP</i> , 102 F.Supp.2d 237 (D.N.J. July 6, 2000).....	41
<i>Estate of Bennett v. Wainwright</i> , 548 F.3d 155, 178 (1st Cir.2008).....	64
<i>Farberware, Inc. v. Groben</i> , 764 F.Supp. 296 (S.D.N.Y. May 16, 1991).....	40
<i>Fingles v. Continental Cas. Co.</i> , 2010 WL 1718289 (E.D.Pa. Apr. 28, 2010).....	24
<i>Figueroa v. Sharper Image Corp.</i> , 517 F.Supp.2d 1292 (S.D.Fla. Oct. 11, 2007).....	50
<i>Flores v. Shapiro &amp; Kreisman</i> , 246 F.Supp.2d 427 (E.D.Pa. Oct. 29, 2002).....	24
<i>Franklin Music Co. v. American Broadcasting Companies</i> , 616 F.2d 528 (3d Cir.1979).....	65
<i>Freedom Med. Inc. v. Gillespie</i> , 634 F.Supp.2d 490 (E.D.Pa. Aug. 29, 2007).....	37
<i>Friends of the Earth, Inc. v. Laidlaw Environmental Services, Inc.</i> , 528 U.S. 167 (2000).....	15, 28,30,63
<i>GFSI. Inc. v. J. Loong Trading, Ltd.</i> , 505 F.Supp.2d 935 (D. Kan. Apr. 25, 2007).....	52
<i>Griffin-El v. Beard</i> , No. 06-2719, 2009 WL 3233151 (E.D.Pa. Oct. 6, 2009).....	13
<i>Gross v. Shep Brown's Boat Basin</i> , No. 99-140, 2000 WL 1480373 (D.N.H. Feb. 28, 2000).....	57
<i>Gross v. Waywell</i> , 628 F.Supp.2d 475 (S.D.N.Y. June 16, 2009).....	39
<i>Hernandez v. CIBA-GEIGY Corp. USA</i> , 2000 WL 33187524 (S.D. Tex. Oct. 17, 2000).....	64

<i>H.J. Inc. v. Northwestern Bell Tel. Co.</i> , 492 U.S. 229 (1989).....	40
<i>Hoffman v. Rashid</i> , 2009 WL 5084098 (E.D. Pa. Dec. 28, 2009).....	20
<i>Hughes v. Consol-Pennsylvania Coal Co.</i> , 945 F.2d 594 (3d Cir.1991).....	40
<i>Hurley v. Atlantic City Police Dep’t.</i> , 174 F.3d 95 (3d Cir.1999).....	64
<i>In re Advanta Corp. Sec. Litig.</i> , 180 F.3d 525 (3d Cir.1999).....	24
<i>In re Am. Investors Life Ins. Co. Annuity Mktg. &amp; Sales Practices Litig.</i> , 2006 WL 1531152 (E.D. Pa. June 2, 2006).....	35
<i>In re. Bath and Kitchen Fixtures Antitrust Litigation</i> , No. 05-cv-00510, 2006 WL 2038605 (E.D.Pa. July 19, 2006).....	12
<i>In re Busiperone Patent Litig.</i> , 185 F.Supp.2d 363 (S.D.N.Y. Feb. 14, 2002).....	31
<i>In re. Ford Motor Co. Ignition Switch Prods. Liab. Litig.</i> , Nos. 96-13125, 96-1814, 96-3198, 2001 WL 1266317 (D.N.J. Sept. 30, 1997).....	16,17
<i>In re General Motors Corporation Pick-Up Truck Fuel Tank Products Liability Litigation</i> , 55 F.3d 768 (3d Cir.1995).....	<i>passim</i>
<i>In re Ins. Brokerages Antitrust Litig.</i> , 618 F.3d 300 (3d Cir.2010).....	34,35
<i>In re Mattel</i> , 588 F.Supp.2d 1111 (C.D.Cal. Dec. 8, 2008).....	63
<i>In re Neurontin Marketing, Sales and Practices Prods.</i> , 433 F.Supp 172 (D.Mass. 2006).....	32
<i>In re NVIDIA GPU Litig.</i> , No. 09-4312, 2009 WL 4020104 (N.D.Cal. Nov. 19, 2009).....	56
<i>In re. Pharmaceutical Industry Average Wholesale Price Litig.</i> , 233 F.R.D. 229 (D.Mass. Jan.30, 2006).....	31
<i>In re. Rockefeller Center Properties, Inc.</i> , 311 F.3d. 198, 215 (3d. Cir. 2002)...	13
<i>In re Schering-Plough Corp. Intron/Temodar Consumer Class Action</i> , No. 2:06-cv-5774 (SRC), 2009 WL 2043604 (D.N.J. July 10, 2009).....	33
<i>In re Whirlpool Corp., Front Loading Washer Products Liab, Litig.</i> , 684 F. Supp. 2d 942 (N.D.Ohio Nov. 4, 2009).....	66
<i>Jaguar Cars, Inc. v. Royal Oaks Motor Car Co., Inc.</i> , 46 F.3d 258 (3d Cir. 1995)....	43
<i>Johnson v. Guhl</i> , 357 F.3d 403 (3d Cir.2004).....	17

<i>Johnson v. Interstate Transit Lines</i> , 163 F.2d 125 (10th Cir. 1947).....	67
<i>Jones v. Select Portfolio Servicing, Inc.</i> , No. 08-972, 2008 WL 1820935 (E.D.Pa. May 21, 2007).....	23
<i>Jordan v. Fox, Rothschild, O'Brien &amp; Frankel</i> , 20 F.3d 1251, 1261 (3d Cir.1994).....	12
<i>Kline v. Sec. Guards, Inc.</i> , 386 F.3d 246 (3d Cir.2004).....	63
<i>Kolar v. Preferred Real Estate Investments, Inc.</i> , No. 07-3864, 2008 WL 2552860 (E.D.Pa. June 19, 2008).....	24
<i>Levine v. First Am. Title Ins. Co.</i> , 682 F.Supp.2d 442 (E.D. Pa. Jan. 14, 2010)...	38
<i>Lorenz v. CSX Corp.</i> , 1 F.3d 1406 (3d Cir.1993).....	42
<i>Los Angeles v. Lyons</i> , 461 U.S. 95 (1983).....	15
<i>Lujan v. Defenders of Wildlife</i> , 504 U.S. 555 (1992).....	14,20
<i>Maio v. Aetna, Inc.</i> , 221 F.3d 472 (3d Cir.2000).....	32
<i>Mann v. Weyerhaeuser Co.</i> , 703 F.2d 272 (8th Cir. 1983).....	23,30
<i>Markovich v. Bell Helicopter Trexton</i> , 805 F.Supp. 1231 (E.D.Pa. April 6, 1992).....	58
<i>Maryland Cas. Co. v. Pac. Coal &amp; Oil Co.</i> , 312 U.S. 270 (1941).....	67
<i>McCalley v. Samsung Electronics Amer. Inc.</i> , 2008 U.S. District LEXIS 28076 (D.N.J.2008).....	56
<i>McCracken v. Exxon/Mobil Co.</i> , No. 08-2932, 2009 WL 3822041 (E.D.Pa. Nov. 12, 2009).....	13
<i>Miller v. Group Voyager, Inc.</i> , 912 F.Supp 164 (E.D.Pa. January 26, 1996).....	58
<i>Monroe v. Beard</i> , 536 F.3d 198 (3d Cir.2008).....	12
<i>Nash v. Shannon</i> , No. 07-160, 2007 WL 1366778 (M.D.Pa. May 7, 2007).....	23
<i>New Jersey Peace Action v. Bush</i> , 379 Fed.Appx. 217 (3d Cir.2010).....	19
<i>Ortiz v. Fibreboard Corp.</i> , 527 U.S. 815 (1999).....	31
<i>Parry v. Westmoreland County</i> , 2010 WL 5798101(W.D.Pa. Nov. 9, 2010).....	20



<i>Phillips v. County of Allegheny</i> , 515 F.3d 224, 231 (3d Cir.2008).....	12,13
<i>Pub. Interest Research Group of N.J., Inc. v. Magnesium Elektron, Inc.</i> , 123 F.3d 111 (3d Cir.1997).....	14
<i>Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.</i> , 913 F.2d 64, 72 (3d Cir.1990).....	20
<i>Quality Air Services, LLC v. Milwaukee Valve Co., Inc.</i> , 671 F.Supp.2d 36 (D.D.C. 2009).....	54
<i>Reves v. Ernst &amp; Young</i> , 507 U.S. 170 (1993).....	37
<i>Rolo v. City Investing Co. Liquidating Trust</i> , 155 F.3d 644 (3d Cir.1998).....	24,39
<i>Salinas v. United States</i> , 522 U.S. 52 (1997)	
<i>San Diego County Gun Rights Comm. v. Reno</i> , 98 F.3d 1121 (9th Cir.1996).....	15
<i>Sedima, S.P.R.L. v. Imprex Co., Inc.</i> , 473 U.S. 479 (1985).....	31,32
<i>Seldon v. Home Loan Services</i> , 647 F.Supp.2d 451 (E.D.Pa. Aug. 4, 2009).....	24
<i>Seville Indus. Machinery Corp. v. Southmost Machinery Corp.</i> , 742 F.2d 786 (3d Cir.1984).....	24,39
<i>Scheuer v. Rhodes</i> , 416 U.S. 232 (1974).....	13
<i>Sheet Metal Workers Nat. Fund v. Amgen Inc.</i> , No. 07-5295, 2008 WL 3833577 (D.N.J. Aug. 13, 2008).....	31
<i>Sheet Metal Workers Local 441 Health &amp; Welfare Plan v. GlaxoSmithKline, PLC</i> , 263 F.R.D. 205, 210 (E.D.Pa. Nov. 2, 2009).....	14
<i>Sikkelee v. Precision Airmotive Corp.</i> , 2011 WL 1344635 (M.D.Pa. April 8, 2011).....	20
<i>Snyder v. ISC Alloys, Ltd.</i> , 772 F.Supp. 244 (W.D.Pa. Aug.16, 1991).....	58
<i>Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.</i> , 171 F.3d 912 (3d Cir.1999).....	66
<i>Stearns v. Select Comfort Retail Corp.</i> , No. 07-2746, 2009 WL 1635931 (N.D.Cal. June 5, 2009).....	50,54,57
<i>Stella v. LVMH Perfumes and Cosmetics</i> , 564 F.Supp.2d 833 (N.D.Ill. July 8, 2008).....	56

<i>Szelc v. Stanger</i> , 2011 WL 1467187 (D.N.J. April 18, 2011).....	64
<i>Tabas v. Tabas</i> , 47 F.3d 1280 (3d Cir.1995).....	41
<i>Tellabs, Inc. v. Makor Issues &amp; Rights, Ltd.</i> , 551 U.S. 308 (2007).....	12
<i>The Pitt News v. Fisher</i> , 215 F.3d 354 (3d Cir.2000).....	20,22
<i>Tietzworth v. Sears</i> , 720 F. Supp.2d 1123 (N.D.Cal. Mar. 31, 2010).....	54
<i>Toll Bros., Inc. v. Township of Readington</i> , 555 F.3d 131,142 (3d Cir.2009).....	19
<i>True v. American Honda Motor Co.</i> , 749 F.Supp.2d 1052 (C.D.Cal. Feb. 26, 2010)....	49,50
<i>University of Maryland at Baltimore v. Peat, Markwic, Main &amp; Co.</i> , 996 F.2d 1534 (3rd Cir. 1993).....	30, 37
<i>U.S. v. Fisher-Otis Co., Inc.</i> , 496 F.2d 1146 (10 <sup>th</sup> Cir.1974).....	67
<i>United States v. Hannigan</i> , 27 F. 3d 890 (3d Cir.1994).....	30,38
<i>U.S. v. Pelullo</i> , 964 F.2d 193 (3d Cir.1992).....	40
<i>U.S. v. Turkette</i> , 452 U.S. 576 (1981).....	34
<i>Vassalotti v. Wells Fargo Bank, N.A.</i> , 732 F.Supp.2d 503 (E.D.Pa.Aug.9, 2010).....	24
<i>Victory Outreach Center v. Meslo</i> , No. Civ.A. 00-5185, 2002 WL 1560242 (E.D.Pa. July 1, 2002).....	24
<i>Vt. Agency of Natural Res. v. United States ex rel. Stevens</i> , 529 U.S. 765 (2000).....	20
<i>Willred Co. v. Westmoreland Metal Mfg. Co.</i> , 200 F.Supp. 59 (E.D.Pa.Oct. 4, 1961)....	52
<i>Whitmore v. Arkansas</i> , 495 U.S. 149 (1990).....	15
<i>Zurawski v. Southeastern Pennsylvania</i> , No. 2:08-cv-05040, 2010 WL 1946922 (E.D.Pa. May 10, 2010).....	13
<i>6000 S Corp. v. Kelly Energy Sys., Inc.</i> , No. C95-1804VRW, 1996 U.S. Dist. LEXIS 15205,(N.D.Cal. Sept. 13, 1996).....	29
<b>STATE CASES</b>	
<i>Aas v. Superior Court</i> , 24 Cal.4th 627, 12 P.3d 1125 (Cal.2000).....	60,61

<i>Banco Popular N. Am. v. Gandi</i> , 876 A.2d 253 (N.J. 2005).....	64
<i>Board of Education of the City of Asbury Park v. Hoek</i> , 183 A.2d 633, 647 (N.J. 1962).....	64
<i>Burrus v. Itek Corp.</i> , 46 Ill. App. 3d 350, 4 Ill. Dec. 793, 360 N.E.2d 1168 (1977)...	30
<i>Carbo Industries v. Becker Chevrolet</i> , 112 A.D.2d 336, 491 N.Y.S.2d 786 (N.Y.App.Div.1985).....	52
<i>Cardinal Health 301, Inc. v. Tyco Elecs. Corp.</i> , 169 Cal.App.4 <sup>th</sup> 116, 87 Cal.Rptr.3d 5 (2008).....	54
<i>Churrica v. Miami Jai-Alai, Inc.</i> , 353 So.2d 547 (Fla.1978).....	65
<i>Davies v. Krasna</i> , 14 Cal.3d 502 (Cal.1975).....	61
<i>Duff v. Bonner Building Supply Inc</i> , 103 Idaho 432, 649 P2d 391 (Idaho App., 1982).....	45,52
<i>Hibbs v. Jeep Corp.</i> , 666 S.W.2d 792 (Mo. Ct. App. 1984).....	29
<i>Jimenez v. Superior Court</i> (2002) 29 Cal.4th 473, 58 P.3d 450 (Cal.2002).....	61
<i>Johnson v. Microsoft Corp.</i> , 106 Ohio St.3d 278, 834 N.E.2d 791 (Ohio 2005).....	66,67
<i>KB Home v. Superior Court</i> , 112 Cal.App.4th 1076, 5 Cal.Rptr.3d 587 (Cal.App.2 Dist. 2003).....	61
<i>Massey-Ferguson Inc v. Laird</i> , 432 So.2d 1259 (Ala. 1983).....	29,30
<i>Mohler v. Jeke</i> , 407 Pa.Super. 478, 595 A.2d 1247 (1991).....	59
<i>Morgan v. Union County Board of Chosen Freeholders</i> , 633 A.2d 985, 999 (N.J. Super. 1993).....	64
<i>Mountaineer Contractors Inc v Mountain State Mack Inc.</i> , 165 W.Va. 292, 268 S.E.2d 886 (W.Va. 1980).....	45
<i>Polaris Indus., Inc. v. McDonald</i> , 119 S.W.3d 331 (Tex.App.-Tyler,2003).....	44
<i>Seely v. White Motor Co.</i> , 63 Cal.2d 9, 403 P.2d 145 (Cal.1965)	
<i>Thiedmann v. Mercedes-Benz USA, LLC</i> , 872 A.2d 783, 795 (N.J. 2005).....	18

*Vintage Homes Inc. v. Coldiron*, 585 S.W.2d 886 (Tex. Civ. App. 1979).....30

## **STATUTES**

### **FEDERAL STATUTES**

U.C.C. §2-714(2).....23

U.C.C. §2-715(1).....51,53

U.C.C. §2-719(1).....22

15 U.S.C. § 2301(5).....57

15 U.S.C. § 2310(d)(1).....57

15 U.S.C. § 2310 (d)(3).....56

15 U.S.C. § 2310(e).....58

18 U.S.C. §1964(c).....32

28 U.S.C. §1332.....56

28 U.S.C. 1332 (d)(2)(A).....56

28 U.S.C. 1712.....48

28 U.S.C.A. § 2202.....67,68

### **STATE STATUTES**

13 Pa. Con. St. § 2714(b).....45

N.Y.U.C.C. § 2-714(2).....45

Tex. Bus. & Com. Code § 2-714(b).....44,45

### **OTHER SOURCES**

5 Wright & Miller, FEDERAL PRACTICE AND PROCEDURE § 1202, 94-95  
(3d ed.2004).....23

Pub.L. 91-452, § 904(a), 84 Stat. 947.....32

Plaintiffs, by and through their undersigned attorneys, respectfully submit this Omnibus Memorandum of Law in Opposition to the Motions to Dismiss Plaintiffs' Consolidated Amended Civil Consumer Class Action Complaint ("CAC") filed by Defendants.

## **I. INTRODUCTION**

This action was brought by Plaintiffs, mothers and fathers of sick children and other consumers, to recover drug payments and overpayments made from at least December 2008 through the present, and for declaratory and other equitable relief, resulting from Defendants' unlawful conduct involving the manufacture, distribution, marketing, promotion and sale of consumer products used to treat ailments in children and adults, and the suppression and concealment of material information concerning such products. Among other things, Defendants failed to inform Plaintiffs that the products were not of the quality and condition as represented at the time of sale, and that they had potentially harmful effects resulting from the undisclosed manufacturing defects and deficiencies, such as "superdosing", particulate matter, and other deficiencies.

Plaintiffs' CAC alleges that, for years, the J&J Defendants marketed and sold their Subject Products to consumers located throughout the United States and other places for their own use and for use by their children. The CAC further alleges that these sales were at prices higher than those otherwise available for comparable products, based in large part upon the purported reputation of the J&J Defendants for producing safe and effective medications, a reputation that allowed the J&J Defendants to charge premium prices long after these products became available in generic form at retail outlets.

Plaintiffs contend that consumers traditionally have been willing to pay more money for J&J and McNeil brand-name Subject Products based in part upon consumers' trust in such

reputation. That is one reason why the failure of the J&J Defendants to timely notify consumers about the truth of the serious degradation of the quality and condition of the Subject Products has caused harm to consumers: consumers continued to pay inflated, premium prices for all Subject Products, not just those products the J&J Defendants chose to recall when government scrutiny became too great to avoid public disclosure (“Recalled Subject Products”).

Plaintiffs further contend that the J&J Defendants were directly assisted in effectuating their unlawful conduct by the Contractor Defendants, who orchestrated and carried out at least one clandestine “phantom recall,” as well as other actions designed to prevent widespread public awareness and a full-blown recall of J&J Defendants’ Subject Products.

The J&J Defendants seek to have this Court dismiss, with prejudice, Plaintiffs’ claims on grounds that, *inter alia*, the CAC is facially deficient because Plaintiffs purportedly did not allege injury with the sufficiency J&J demands. *See* J&J Mem. at 2. Additionally, the J&J Defendants claim that Plaintiffs’ averments that the refunds, to the extent they were made available at limited times, for limited products, to a limited sub-set of the Class of consumers, did not fully reimburse Plaintiffs and Class Members is ambiguous and thus “impossible to discern the particulars and scope” of the allegation. *Id.* at 3. The fact is that the CAC provides more than adequate notice of Plaintiffs’ claims and sufficient detail to allow the J&J Defendants to prepare to defend this case. Nothing more is required at this stage of the proceedings.

The J&J Defendants further claim that, notwithstanding Plaintiffs’ allegations that the J&J Defendants sold smelly, adulterated, contaminated, and dangerous products to Plaintiffs and the Class, there is no harm or injury unless the “medicine did not work or cause(d) physical injury.” *See id.* at p.4. Thus, the J&J Defendants seek to minimize the defective nature of the Subject Products, the seriousness of the quality problems associated with those products, and the

subsequent sale of those sub-standard products to Plaintiffs and the Class without full disclosure of their actual degraded condition. *See* J&J Mem. at 1.

J&J should not require people to be seriously injured or killed before they do the right thing and refund their customers the hard-earned dollars they paid for admittedly sub-standard products. Instructively, while the J&J Defendants admit that their products were defective at the time they were sold, they highlight the fact that “the market withdrawal and product recalls were not prompted by adverse medical events.” *Id.* In other words, it does not matter to J&J that Plaintiffs and the Class purchased and used, for themselves and their infant children at a time when they were ill and in need of safe and efficacious medicines, filthy, adulterated, contaminated, and sub-standard products that were not of the quality and condition as represented at the time of sale. It does not matter to J&J that they continued to charge premium prices for such sub-standard products, trading on the name and past reputation of McNeil. It does not matter to J&J that Plaintiffs and the Class have not been refunded the money they paid for products that had to be discarded as unsafe for consumption and otherwise worthless, all due to J&J’s misconduct. Instead, the J&J Defendants embrace the good fortune that there have been no widely reported adverse medical events and health risks associated with their dissemination of the sub-standard products as grounds for claiming Plaintiffs and the Class have not suffered injury. *See Id.* The J&J Defendants are wrong.

In an unseemly display of trying to “blame the victim”, the J&J Defendants try to deflect attention from themselves by pointing to a “litigious” society as reason for Plaintiffs’ interest in seeking appropriate redress for their damages. They suggest that because J&J purportedly took “reasonable steps to ensure that consumers who purchased recalled products were made whole,” that should “be the end of the story.” *Id.* In fact, as Plaintiffs point out in their CAC, “the story”

of this case begins with J&J's irresponsible behaviour both before and after it issued its limited public recall of certain children's medications in April 2010. Unlike how the J&J of old handled the unfortunate incident of an outsider tampering with its Tylenol product in the 1980s, the current J&J (with Defendants Weldon, Goggins and others at the helm) took a decidedly different path: they chose to try to minimize the damage to J&J's bottom line at all costs by delaying proper disclosure of the problem, downplaying the nature and scope of the problem when they were forced by the FDA to act, and then diminishing the amount of the relief afforded to affected consumers by offering worthless, non-transferrable coupons on the purchase of future McNeil products and limited monetary refunds of part of their cash outlay.

Indeed, as the CAC sets forth in detail, only a subset of purchasers of the Recalled Subject Products who could meet the stringent eligibility criteria established unilaterally by J&J and McNeil could receive such a refund. J&J's self-serving statements address only the Recalled Subject Products and ignore the other Subject Products which Plaintiffs' allege suffer from the same deficiencies as the Recalled Subject Products<sup>1</sup>. Thus, Plaintiffs had every right to seek redress for their damages under the law, litigious society or not.

The Contractor Defendants, for their part, attempt to downplay and minimize their respective roles in assisting the J&J Defendants in the unfair and deceptive acts and practices as alleged in Plaintiffs' CAC. *See* Contractor Mem. at 1. Indeed, the Contractor Defendants characterize their involvement as "peripheral . . . to the conduct underlying this action." *Id.* At

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<sup>1</sup> Indeed, the Court can and should take judicial notice that, since the time of the filing of the CAC, the J&J Defendants have instituted at least five (5) additional recalls of their products including a March 29, 2011 recall of Tylenol, Sudafed and Benadryl products. *See* [www.mcneilproductrecall.com/page.jhtml?id=/include/news-march-2011.inc](http://www.mcneilproductrecall.com/page.jhtml?id=/include/news-march-2011.inc), last visited on May 12, 2011. Thus, as time goes on, the full nature and scope of J&J's problems respecting the Subject Products has come to further light, proving Plaintiffs' point that the problem is far bigger than J&J concedes.



its core, however, the Contractor Defendants' claim that their so-called "peripheral" actions somehow vitiate any liability on their part.

Plaintiffs' CAC clearly implicates the Contractor Defendants in a widespread scheme with the J&J Defendants to conceal the truth about the filthy, adulterated, contaminated and sub-standard nature of the Subject Products to avoid public disclosure and scrutiny and to minimize the financial burden of a widespread consumer recall of these defective Subject Products. The Contractor Defendants are alleged to have done this by conducting, *inter alia*, clandestine "phantom" recalls and other market assessments to consult with and advise J&J about how to proceed to minimize the damage, rather than to do the right thing. *See* CAC at ¶¶4, 63, 64, 65, 66, 145-154, and Ex. E.

The Contractor Defendants further allege in their Motion to Dismiss that their activities on behalf of and in concert with the J&J Defendants allegedly did not violate state and federal law. *See* Contractor Dfts. Mem. at 1. Notwithstanding Plaintiffs' well-pled allegations to the contrary, it is notable that these very activities by the Contractor Defendants are the subject of a pending congressional investigation. *See* CAC at ¶154. At this juncture, the Contractor Defendants' self-serving statements about the alleged legality of their actions are not a proper consideration on a motion to dismiss. Instead, Plaintiffs should be given the opportunity to conduct discovery into these claims.

When viewed in its totality, and as argued more fully below, Plaintiffs' CAC alleges necessary facts to satisfy the pleading standards under Rule 8 (and Rule 9, to the extent certain specificity is required for fraud). The J&J Defendants' and the Contractor Defendant's Motions to Dismiss should be denied.

## II. SUMMARY OF FACTS

As Plaintiffs alleged in the CAC, on April 30, 2010, the Food and Drug Administration (“FDA”) issued a report regarding an inspection that FDA inspectors performed at McNeil’s Ft. Washington, Pennsylvania manufacturing plant. CAC at ¶¶ 6, 202 and Ex. C thereto. The FDA report detailed 20 major observations regarding serious deficiencies in McNeil’s manufacturing processes, including, *inter alia*, failures of production controls regarding strength, quality and purity of the products manufactured, the use of raw materials with “known contaminations”, including materials “contaminated with gram-negative organisms”, super potency of products, of products containing “foreign material, particulate matter and/or contamination,” dust, debris and a general lack of cleanliness in the quality control unit, and a lack of record keeping. CAC at ¶¶ 6, 203.

On that same day, the J&J Defendants publicly revealed for the first time that they had had been flagrantly violating the rules and regulations established by the FDA to protect consumers from harmful drug products being sold in this country. CAC at ¶ 5. Indeed, on that day, the J&J Defendants confirmed that their McNeil operating company had been cited by the FDA for twenty (20) major violations in its manufacturing processes, exposing innocent children throughout the country and other places to adulterated, contaminated, filthy and dangerous products which never should have been sold, but which remained in the open market and in the cupboards of consumers throughout the country. *Id.* Instructively, these violations had been ongoing at the company for years, and they continued unabated and undisclosed until the April 30, 2010 FDA report<sup>2</sup>. CAC ¶¶ 5, 206-209.

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<sup>2</sup> Notably, it was this April 30, 2010 recall that spurred the House Committee on Oversight and Government Reform in Congress to conduct an investigation and hold two public hearings. CAC at ¶¶ 210-223.

As a result of the FDA's inspections and report, a recall was issued by McNeil for a subset of the Subject Products at issue in this case, and only as to certain select few National Drug Codes ("NDCs"), production dates and lot numbers<sup>3</sup>. CAC at ¶¶ 7, 10, 232. As alleged in the CAC, J&J and McNeil deliberately delayed announcing such recall until late in the evening so as to avoid substantial media attention—and with it, widespread disclosure to consumers—and to minimize the J&J Defendants' exposure to having to pay full cash refunds to concerned consumers. *Id.* As a result, only a small portion of the consumers who purchased the Subject Products have ever learned about the recall. CAC at ¶ 8. Plaintiffs further allege in the CAC that, notwithstanding the late released recall announcement, the J&J Defendants did not recall all of the Subject Products affected by their conduct, and are not offering all consumers in the consumer Class full cash refunds of their out-of-pocket payments made for all Subject Products – only the select few Recalled Subject Products chosen by Defendants. CAC at ¶ 11.

As Plaintiffs allege in the CAC, at some point after the recall announcement was made, the J&J Defendants set up a recall website<sup>4</sup>. CAC at ¶¶ 10, 225, and CAC n. 3. The recall website initially offered only select consumers a limited opportunity to request a "high value coupon" or a partial cash refund of part of their out-of-pocket payments made for Recalled Subject Products. CAC at ¶¶ 14, 224 and CAC n.3. Plaintiffs contend based on the limited documents produced by J&J that the customer service representatives were trained to steer consumers to product coupons instead of cash refunds. CAC ¶¶ 241, 244. Such refunds were not offered to all consumers in the Class; instead, such refunds were offered to only those consumers

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<sup>3</sup> Instructively, following the April 30, 2010 recall, through December 9, 2010, the J & J Defendants announced at least eight (8) additional recalls of its products. *See* CAC at ¶¶ 174-191.

<sup>4</sup> [www.mcneilproductrecall.com/page.jhtml?id=/include/replacement\\_coupon.inc](http://www.mcneilproductrecall.com/page.jhtml?id=/include/replacement_coupon.inc), last visited January 4, 2011. *See* n.3 of CAC.

who could meet the stringent eligibility criteria established exclusively by J&J and McNeil without any external oversight, judicial or otherwise. CAC at ¶¶ 227-230, 233. Instructively, the J&J Defendants' recall website directed consumers to dispose of the products and packaging, and provided very specific instructions on how to properly dispose of said products, the very information J&J demands as a prerequisite to participation in the refund program. CAC at ¶ 13.

The J&J Defendants pushed the worthless coupons over cash. CAC at ¶¶ 241, 244. Thus, Plaintiffs have alleged as part of their CAC that some members of the consumer Class in this case received these worthless coupons instead of a full cash refund, and therefore have not been adequately compensated for their losses as a result of the J&J Defendants' conduct. CAC at ¶ 241. For those who received cash, Plaintiffs allege they did not receive the total of their cash outlay.

Subsequent to the April 30, 2010 FDA report, the FDA on December 9, 2010, issued another report pertaining to yet another FDA inspection of the Ft. Washington plant. CAC at ¶ 204 and Ex. D thereto. This report listed seven (7) additional observations including that "[t]he responsibilities and procedures applicable to quality control units are not fully followed." CAC at ¶ 205.

This lawsuit was initiated on May 12, 2010, in the wake of the above. Subsequent to the filing of the first action, additional related actions were filed across the country.<sup>5</sup> On October 8, 2010, these related actions were transferred by the Judicial Panel on Multidistrict Litigation to

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<sup>5</sup> Actions were filed on behalf of Amber Coleman, Dana Rivera, Wayne Burrell, Landy Nyuyen, Justin Michaud, Jennifer DeGroot, Emile and Amber Roberson and John Smith in the United States District Court for the Districts of Ohio (Western Division), September 16, 2010; Central District of California, July 16, 2010; and six (6) separate actions in the Northern District of Illinois (Eastern Division), July 8, 2010.

the Eastern District of Pennsylvania for coordinated or consolidated pre-trial proceedings as MDL 2190. *See* 10/8/10 Transfer Order<sup>6</sup>.

On December 13, 2010, this Court held its first status conference. During that status conference, Plaintiffs' requested that the J&J Defendants produce a readymade set of documents that the J&J Defendants had previously produced to the FDA and to Congress. *See* 12/13/2010 Tr. 22:10-23. The J&J Defendants opposed such production, not on the basis of burden, but on grounds that the documents allegedly were not relevant and would not be helpful to the issues. 12/13/2010 Tr. 37:7-41:24. This Court did not agree with the J&J Defendants' assessment, and ordered them to produce documents. 12/13/2010 Tr. 51:7-19.

The J&J Defendants thereafter produced a sum total of ninety-eight (98) pages of documents (that is 98 total pages, not 98 documents) in response to this Court's directive. *See* CAC Ex. B. The vast majority of these pages are printed out screen shots from J&J's websites, which raises the simple, threshold question - if you are a consumer without internet access, or one simply not inclined to use the internet, how were you ever to learn of the recall, let alone the details of how to access the refund program? As this Court is well aware, class settlements include mandatory, court-approved notice to class members in the mail, newspapers, magazines, and other means to ensure fulsome notice to all those potentially affected. J&J's recall program includes no such medium of notice to consumers, and, on its face, is inadequate to support J&J's assertions in its pending Motion.

In its April 30, 2010 press release (McNeil –MDL-0000001-02), J&J confirms (at the very outset of its recall) roadblocks were created to consumers inquiring into the recall: “due to the high call volume, it may take longer than normal to get through to our live call center.”

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<sup>6</sup> On March 24, 2010, the Panel conditionally transferred an additional related action, one brought by the Attorney General of the State of Oregon against J & J. *See* 2/24/2010 CTO-3.

Moreover, the press release contains no details as to the J&J refund program; the only reference is to a one line “click here” link to “request a refund or product coupon” appearing at the very end of the release. McNeil-MDL-0000002. A similar, buried reference to a possible refund appears in McNeil-MDL-00000003-04, an apparent May 1, 2010 snapshot of a J&J-maintained website. This document provides no details, only a reference to the McNeil Product recall website and that a refund or coupon can be requested. There is no confirmation of when a consumer is eligible for a refund or coupon, the value of the same, or when the same will be issued, if at all (it does not state you *will* received a refund, only that you *can* request one, confirming it is in J&J's discretion to grant (or deny) that request).

The internet blog that follows in the produced documents is also very telling. Consumers confirm their frustration in being able to reach anyone at the J&J hotline, which difficulty is again acknowledged by J&J, but there is no indication in any of the documents that J&J produced that the situation was ever rectified (even knowing full well that a measurable percentage of consumers, having difficulty trying to reach a person on the hotline, would not try again out of pure frustration). Needless to say, a hotline set up with too few operators, operators with little substantive knowledge, and/or operators trained to make it difficult to receive a cash refund is unacceptable as it only serves to minimize the relief to consumers. This is far from the robust program the Defendants described to the Court at the initial conference. It is far from the sort of program this Court would approve under a court-sponsored resolution of the classwide claims at issue.

A May 13, 2010 “update” issued to healthcare providers (not to consumers), references the coupon program and a refund for “the average retail price” of the product. Average, by definition (although J&J offers no definition of how it came to calculate these supposed average

retail prices), necessarily under compensates those consumers who paid amounts above that average. This alone undermines J&J's claim of providing full compensation.

The McNeil-MDL-00000017-18 document, titled "U.S. McNeil Pediatric Liquids Recall, Compensation Guidelines," is also relevant to the Court's consideration of the defense Motions in that it establishes J&J's efforts to conceal any acknowledgement to consumers that the coupon may never be redeemable and may be forever valueless. It shows J&J's concerted efforts to push the coupon over a cash-based refund. J&J operators were not to voluntarily advise inquiring consumers about the plant closures and when they may reopen, unless the consumer specifically asks these very questions. If the consumer does not ask, the coupon is to be issued to a deliberately ill-informed consumer. The mandated script also confirms that a refund check is available, but only after the consumer has decided he/she "does not want to wait for the product to be available to receive reimbursement...." *See* McNeil-MDL-00000017.

A similar document is McNeil-MDL-00000015-16, which appears to be intended for retailers only, not the general public/consumers (i.e., the document is entitled "McNeil Pediatric Recall, Compensation Guidelines & Information for Retailers"). It is also marked as "Version:2", but J&J's production provides no documents relating to earlier draft or edited versions, let alone meeting minutes or notes concerning internal discussions as to this document's creation or purpose. In fact, the 98-page production by J&J contains no such documents, no call notes for the hotline, and no internal documents reflecting the refund program, or its creation, administration, results, etc. Needless to say, Plaintiffs would be entitled to such materials in discovery. These documents highlight J&J's ongoing effort to push un-redeemable, worthless coupons over full cash refunds, as called for by this lawsuit.<sup>7</sup>

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<sup>7</sup> McNeil-MDL-00000063-64 raises even further questions concerning J&J pushing of coupons over cash refunds. This document notes a "change" in "compensation policy" and states that

As a result of the above, Plaintiffs filed their Consolidated Amended Civil Consumer Class Action Complaint.

### **III.ARGUMENT**

#### **A. Standards for Motions to Dismiss**

To survive a motion to dismiss, a civil plaintiff must allege facts that “raise a right to relief above the speculative level on the assumption that the allegations in the complaint are true (even if doubtful in fact).” *Monroe v. Beard*, 536 F.3d 198, 205 (3d Cir. 2008) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 127 S.Ct.1955 (2007) (internal citations omitted). “A sound complaint must set forth ‘a short and plain statement of the claim showing that the pleader is entitled to relief.’” Fed.R.Civ.P. 8(a)(2). This statement must “give the defendant fair notice of what the ... claim is and the grounds upon which it rests.” *In re Bath and Kitchen Fixtures Antitrust Litigation*, 2006 WL 2038605 at \*3 (E.D.Pa. July 19, 2006)(McLaughlin, J.).

On a motion to dismiss, the court assumes that plaintiffs can prove the facts alleged in their complaint. *Assoc. Gen. Contractors v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983). The court also “must accept all factual allegations as true, construe the complaint in the light most favorable to the plaintiff, and determine whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief.” *See Phillips v. County of Allegheny*, 515 F.3d 224, 231 (3d. Cir.2008). In doing so, a court may look only to the facts alleged in the complaint and any accompanying attachments. *Jordan v. Fox, Rothschild, O’Brien & Frankel*, 20 F.3d 1251, 1261 (3d. Cir.1994). Importantly, “the court must read the instant complaint in its entirety, and must not ‘scrutinize each allegation in isolation but [must] assess all of the allegations holistically.’” *Tellabs, Inc., v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 325, 127 S.Ct. 2499,

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“we want to ensure consumers looking for compensation are offered a check first and then a coupon. At the very least, this document confirms the original focus on pushing the valueless coupons.



168 L.Ed.179 (2007). “In other words, defendants may not ‘cherry pick’ specific allegations in the complaint that might be insufficient standing alone.” *Id.*

Rule 8(a)(2)’s required “showing” is measured by the flexible, “context-specific” facial plausibility standard based on the court’s review of the complaint’s entirety and context, drawing on the court’s experience and common sense. *See Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007) and *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009).<sup>8</sup> “Plausible” does not mean “probable.” “[A] well-pled complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely.” *Twombly*, 550 U.S. at 556. Plausible only means more than “possible” or “conceivable.” *Id.* The CAC need only provide “some [factual] setting” (*Twombly*, 550 U.S. at 557) for plaintiffs’ claims to move from “conceivable” to “plausible.” *See Phillips v. Cty. of Allegheny*, 515 F.3d 224, 234 (3d Cir.2008) (“‘plausibility’ is related to the requirement of a Rule 8 ‘showing,’” *citing Twombly*, 550 U.S. at 556 n.3).

Dismissal under Rule 12(b)(6) for failure to state a claim is limited to those instances where it is certain that no relief could be granted under any set of facts that could be proved. *Id.* Ultimately, however, “the question is not whether plaintiff will prevail at trial, but whether they should be given an opportunity to offer evidence in support of their claims.” *In re Rockefeller Center Properties, Inc.*, 311 F.3d.198, 215 (3d. Cir.2002)(citing *Scheuer v. Rhodes*, 416 U.S. 232, 236, 94 S.Ct. 1683, 40 L.Ed.2d 90 (1974), overruled on other grounds.

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<sup>8</sup> *See, e.g., Atiyeh v. National Fire Ins. Co. of Hartford*, 742 F.Supp.2d 591, 596 (E.D.Pa. Sept. 27, 2010); *Griffin-El v. Beard*, 2009 WL 3233151 (E.D.Pa. Oct. 6, 2009); *Zurawski v. Southeastern Pennsylvania*, 2010 WL 1946922 (E.D.Pa.); *McCracken v. Exxon/Mobil Co.*, 2009 WL 3822041 (E.D.Pa. May 10, 2010).

Whether plaintiffs should be given an opportunity to offer evidence in support of their claims is a question that must be decided by considering the entirety of the record before this Court. The CAC incorporates several other documents that set forth in great detail the nature and extent of Defendants' unfair and deceptive acts and practices, for which Plaintiffs seek to hold the Defendants liable. *See Buck v. Hampton Twp. Sch. Dist.*, 453 F.3d 256, 260 (3d Cir.2006) ("In evaluating a motion to dismiss, we may consider documents that are attached to or submitted with the complaint... and any matters incorporated by reference or integral to the claim..."). These documents include the following: a list of the "Subject Products" (Ex. A), documents produced by J&J in response to this Court's discovery Order (Ex. B), FDA inspection reports of McNeil's Ft. Washington plant in April, October, and December of 2010 (Exs. C and D), and a Memorandum regarding the scheme between the J&J Defendants and the Contractor Defendants (CSCS and WIS) to purchase Motrin off store shelves in 2009 (Ex E). All of these documents are incorporated in the CAC as if fully set forth therein. Defendants largely fail to address these documents in their moving papers.

#### **B. Plaintiffs Have Standing To Sue the Individual, J&J and Contractor Defendants**

Plaintiffs have standing to bring suit and have properly invoked this Court's jurisdiction under Article III's "case or controversy" requirement. As a preliminary matter, standing "is a threshold jurisdictional requirement, derived from the 'case or controversy' language of Article III of the Constitution." *Pub. Interest Research Group of N.J., Inc. v. Magnesium Elektron, Inc.*, 123 F.3d 111, 117 (3d Cir.1997). In order to meet the requirements for Article III standing, plaintiffs must show, among other things: (a) that they have suffered an injury in fact and (b) causation. *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205, 210 (E.D.Pa. Nov. 2, 2009) (*quoting Lujan v. Defenders of Wildlife*, 504 U.S.

555, 560-61, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992)). To satisfy the “injury in fact” requirement, a plaintiff must “allege a distinct and palpable injury.” *Whitmore v. Arkansas*, 495 U.S. 149, 155, 110 S.Ct. 1717, 109 L.Ed.2d 135 (1990). The injury must be “real and immediate,” rather than “merely abstract, conjectural or hypothetical,” but it need not be substantial. *Los Angeles v. Lyons*, 461 U.S. 95, 101-02, 103 S.Ct. 1660, 75 L.Ed.2d 675 (1983). “Injury-in-fact is not Mount Everest.” *Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 294 (*quoting Bowman v. Wilson*, 672 F.2d 1145, 1151 (3d Cir.1982)) (“The contours of the injury-in-fact requirement, while not precisely defined, are very generous,” requiring only that claimant “allege some specific, ‘identifiable trifle’ of injury”).

Neither the J&J Defendants nor the Contractor Defendants address a potential third requirement<sup>9</sup> for Article III standing. The Contractor Defendants, however, raise concerns about causation for Article III standing, while the J&J Defendants do not. Because both the J&J and Contractor Defendants, in their Motions to Dismiss, do not raise certain issues, they are deemed waived.

### **1. Plaintiffs’ Allegations Show That They Have Suffered Injury In Fact.**

Plaintiffs’ allegations of purchase of the J&J Defendants’ “Subject Products” alone are sufficient to prove that they have suffered an injury in fact. Plaintiffs and the Class suffered actual economic loss via out-of-pocket payments for Subject Products which were not of the same quality and condition as represented at the time of sale and some of which were unsafe. “While it is difficult to reduce injury-in-fact to a simple formula, economic injury is one of its paradigmatic forms.” *Danvers Motor Co., Inc.*, 432 F.3d at 291. *See also San Diego County Gun*

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<sup>9</sup> The Supreme Court has identified a redressability aspect of the standing doctrine. The redressability prong requires a showing that “the injury will be redressed by a favorable decision.” *Friends of the Earth, Inc. v. Laidlaw Environmental Services, Inc.* 528 U.S. 167, 181, 120 S.Ct. 693 (2000).

*Rights Comm. v. Reno*, 98 F.3d 1121, 1130 (9th Cir.1996) (“Economic injury is clearly a sufficient basis for standing.”). Plaintiffs purchased Subject Products as a result of both the J&J and Contractor Defendants negligent and fraudulent scheme to conceal the fact that the Subject Products were defective and/or sub-standard. In fact, Plaintiffs could no longer use the Subject Products as they were rendered worthless after the J&J Defendants made public their deficiencies and issued numerous recalls.

J&J Defendants argue that their offer of refunds and product coupons should destroy the “injury in fact” otherwise pled by Plaintiffs. However, J&J Defendants’ refund offer is completely silent as to how it will calculate refund amounts or the specific amounts to be paid. (The documents produced show that some retail “average” was used without regard for sales taxes or other incidental costs). Furthermore, in order for the consumer to obtain a refund, they are instructed to complete a form in full with required information, including the product name, the National Drug Code (“NDC”) number, lot number and expiration date of the product, all of which can be found on the back or side label of the product. J&J Defendants do not address how consumers who no longer have access to the required information (because they have discarded the products as they were advised to do) would be able to receive a refund. Moreover, it appears that the J&J Defendants stopped reporting the NDCs for the Subject Products, thereby depriving Plaintiffs and the Class of a key piece of information required to obtain a coupon.

J&J Defendants erroneously cite the New Jersey District Court’s decision in *In re. Ford Motor Co. Ignition Switch Prods. Liab. Litig.*, Nos. 96-13125, 96-1814, 96-3198, 2001 WL 1266317 (D.N.J. Sept. 30, 1997) for the proposition that Plaintiffs lack injury in fact in this case. In the *Ford* case, as Defendants point out, the plaintiffs failed to do two (2) things: (1) “[n]one of the plaintiffs alleged that the ignition switch in his or her own vehicle manifested the defect at

issue,” and (2) “as part of the defendant’s recall program, the plaintiffs were entitled to the installation of a replacement ignition switch free of charge.” J&J Mem. at 10 (*citing Ford*, 2001 WL 1266317 at \*5). In this case, in stark contrast, J&J Defendants concede that all of the Recalled Subject Products were defective, apart from Plaintiffs’ unambiguous allegations in their CAC that the “Subject Products, including some Recalled Subject Products..., were unsafe at the time of sale, were not of the same quality and condition as represented at the time of sale, and are now worthless as medicines.” CAC ¶¶28-52. Further, with respect to the recall, J&J Defendants have not offered sufficient compensation to make the Plaintiffs whole.<sup>10</sup> Instead, the J&J Defendants offer coupons on future product purchases which are not presently redeemable (due to the fact that there is no time certain given by the J&J Defendants when any of the Recalled Subject Products will be re-introduced into the market), and the coupons are not transferable, meaning they have no present cash value.

The J&J Defendants also cite the case of *Johnson v. Guhl*, 357 F.3d 403 (3d Cir.2004) to challenge Plaintiffs’ standing. In *Johnson*, the State of New Jersey “‘offered plaintiffs the opportunity to apply for’ the type of hearing they were seeking in the litigation.” J&J Mem. at 10-11 (*citing Johnson*, 357 F. 3d at 411-412). Unlike in *Johnson*, however, the J&J Defendants here are not offering Plaintiffs what they seek in this litigation: full cash refunds and consequential damages. Instead, the J&J Defendants initially offered “high value coupons” on future McNeil products that may never be sold. CAC at ¶ 239 (*quoting* Mr. Owen who stated that the folks handling the customer service lines for J&J were “data collectors and coupon issuers”); 241 (“the bloggers all report that J&J was encouraging a coupon first”); 244 (citing a “Recall Update: that “Effective immediately, we want to ensure consumers looking for

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<sup>10</sup> A blogger named “Aaron L,” in regards to the refund program, is reported as saying “I had to destroy 6 various McNeil products and received a check for \$10.00.” CAC ¶ 241. Accordingly, J&J’s own documentation demonstrates that members of the Class have not been made whole.

compensation are offered a *check first* and then a coupon”). Even when J&J changed their recall policy to offering a “check first” after the recall program was launched and underway, J&J only offered a “refund for the average retail price of the product.” (CAC ¶ 242 *citing* McNeil-MDL-0000012-13). J&J Defendants provide no explanation as to how they calculated the “average retail price,” but it is clear from the limited documents produced that such price did *not* include applicable taxes or other consequential damages. This fact is revealed by the following two documents: McNeil-MDL-0000016 (reporting the retail prices for children’s products at even increments), and McNeil-MDL-0000018 (same). *See* CAC at ¶ 242. Indeed, a later document produced by the J&J Defendants (McNeil-MDL-0000040-41) reveals a discrepancy between what the J&J Defendants calculated to be the average retail prices at various points in time. CAC at ¶¶ 242-243. This shows that the J&J Defendants have offered varying amounts over time, and have not offered Plaintiffs and the Class what they seek in this lawsuit.

Finally, the J&J Defendants cite the cases of *Briehl v. Gen Motor Corps.*, 172 F.3d 623 (8<sup>th</sup> Cir.1999) and *Thiedmann v. Mercedes-Benz USA, LLC*, 872 A.2d 783, 795 (N.J. 2005), attempting to illustrate that where economic loss has not yet manifested or where there is an assertion of future hypothetical loss, there is a lack of standing under Article III. J&J Mem. at 12-13. Unlike the facts in these cases, here, Plaintiffs’ actual economic loss has already manifested. Plaintiffs were expressly advised by J&J to stop using Recalled Subject Products. The actual economic loss accrued then. At J&J’s direction, the Recalled Subject Products had to be discarded and, as a result of this warning and product recall, Plaintiffs have paid or will pay expenses related to the purchase and replacement of Recalled Subject Products. *See American Federation of State County and Municipal Employees v. Ortho-McNeil-Janssen*, 2010 WL 891150 (E.D.Pa. March 11, 2010) (where recall notice warned that “[f]entanyl patches that are

cut or damaged in any way should not be used,” and that “[e]xposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal” and as a result of this warning, and product recall, “Plaintiffs have paid or will pay expenses related to the purchase of [ ] supplies of 25 mcg/hour fentanyl patches that were unusable, worthless, and had to be discarded,” Plaintiffs had pled an economic loss that is “concrete, particular and traceable to a defect resulting from Defendants’ manufacturing and distribution process”).

Furthermore, J&J Defendants argue that Plaintiffs lack standing to represent other individuals who were not fully compensated, citing a string of cases which stand for the proposition that where a drug was not ineffective or unsafe for its prescribed use, plaintiffs’ claims for economic harm must be dismissed. However, J&J Defendants’ argument fails on the record before this Court because, in their recall notices, J&J cautioned “parents and caregivers not to administer these products to their children.” *See* Ex. A to CAC. J&J Defendants specifically advised consumers who purchased the Recalled Subject Products to discontinue use. *Id.* It eludes common sense to suggest that consumers would continue using a product after the manufacturer explicitly advises against continued use.

## **2. Plaintiffs’ Claimed Injuries Have Been Caused By the Conduct of the Contractor Defendants.**

Contractor Defendants’ conduct is “fairly traceable” to Plaintiffs’ injuries. “To meet the causation requirement for standing, a plaintiff must establish “a causal connection between the injury and the conduct complained of.” *New Jersey Peace Action v. Bush*, 379 Fed.Appx. 217, 221 (3d Cir.2010). The plaintiff must establish that the defendant’s challenged actions, and not the actions of some third party, caused the plaintiff’s injury. *Toll Bros., Inc. v. Township of Readington*, 555 F.3d 131,142 (3d.Cir.2009)(quoting *Lujan v. Defenders of Wildlife*, 504 U.S.

555, 560, 112 S.Ct. 2130, 119 L.Ed.2d 351 (1992). This causal connection need not be as close as the proximate causation needed to succeed on the merits of a tort claim. *Id.* (quoting *Pub. Interest Research Group of N.J., Inc. v. Powell Duffryn Terminals Inc.*, 913 F.2d 64, 72 (3d Cir.1990)). Rather, an indirect causal relationship will suffice. *Id.* (quoting *The Pitt News*, 215 F.3d at 361 & n. 4), so long as there is “a fairly traceable connection between the alleged injury in fact and the alleged conduct of the defendant,” *Id.* (quoting *Vt. Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 771, 120 S.Ct. 1858, 146 L.Ed.2d 836 (2000)).

Contractor Defendants’ do not dispute that they knowingly and secretly removed defective and unsafe Subject Products from only select retail outlets as discussed with and agreed upon by J&J Defendants. CAC ¶149 (referencing “lists of retail outlets” for the “phantom recall”). These facts are matters of public record. *See* June 2009 email thread involving WIS personnel attached to the Letter to William C. Weldon, CEO of J&J, from Edolphus Towns, Chairman of the Committee on Oversight and Government Reform of the U.S. House of Representatives (attached hereto as Exhibit “A”).<sup>11</sup> Indeed, the referenced email talks about WIS finishing the phantom recall of Motrin and “exploring another similar but potentially larger recall for July [2009] involving Children’s Tylenol. WIS will look to explore next week the potential quantities in 400 geographically dispersed stores to ‘assess’ the quantities on shelves. ... After

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<sup>11</sup> As the Contractor Defendants likely will complain about going outside the four corners of the CAC, this Court can (and should) take judicial notice of the Letter from Congress. *See Buck v. Hampton Tp. School Dist.*, 452 F.3d 256, 260 (3d Cir. 2006) (In evaluating a motion to dismiss, a court may consider documents that are attached or submitted with the complaint, matters incorporated by reference or integral to the claim, items subject to judicial notice, matters of public record, orders and items appearing in the record of the case); *Hoffman v. Rashid*, 2009 WL 5084098 at \* 2 (E.D. Pa. Dec. 28, 2009); *Parry v. Westmoreland County*, 2010 WL 5798101 at \* 2 (W.D.Pa. Nov. 9, 2010); *Sikkelee v. Precision Airmotive Corp.*, 2011 WL 1344635 at \* 2 (M.D.Pa. April 8, 2011). The investigation by the Committee on Oversight and Government Reform was described in the CAC (see ¶¶ 63, 64, 66, 154, 173, 201, 210-223), though Plaintiffs had not uncovered the subject letter at the time they prepared the CAC. Certainly, there is no prejudice to Contractor Defendants for the truthful facts about the phantom recall to be considered by this Court in the context of its decision on the Motions to Dismiss.



that assessment...J&J could ask InMar/WIS to move ahead on a scope to purchase product that would make our Motrin project look small (thousands vs. the 5000 C-Stores completing now).” In other words, the “phantom recall” of Motrin was done at 5,000 retailers, whereas the anticipated children’s Tylenol recall was to be much larger.

Plaintiffs contend that Contractor Defendants, acting together with the J&J Defendants, unlawfully concealed the fact that the Subject Products Plaintiffs were purchasing were sub-standard and defective. Contractor Defendants acted in concert with J&J Defendants to provide Contractor employees with specific lists of only select retail outlets in major metropolitan areas, and instructed them to visit only those outlets and to purchase all of only select Subject Products from the shelves, like Motrin in 2009. They disguised themselves as “regular customers.” J&J Defendants explicitly advised Contractors Defendants not to discuss the purchases as recalls with anyone. *See* CAC Ex. “E”. Contractor Defendants agreed to take part in this “phantom recall” and aided and abetted the J&J Defendants in negligently and fraudulently concealing the truth from Plaintiffs and the Class.

The fraudulent concealment of the truth directly harmed not only consumers of the Motrin that was pulled from select retail shelves – to the detriment of all others who continued to purchase Motrin that remained on other retail shelves throughout the country – but all the consumers of children’s products, like the Children’s Tylenol that J&J obviously considered recalling way back in June 2009, but did not. Had the J&J and Contractor Defendants done the responsible thing and removed all known, defective Children’s Tylenol from all store shelves in the summer of 2009, potentially millions of consumer Class members would have be spared having purchased defective Children’s Tylenol – especially the “superdosed” Children’s Dye

Free version – in the intervening months until all the children’s products were recalled in April 2010, after the FDA cracked down.

Contractor Defendants argue that they could not have caused the claimed injury to Plaintiffs because they did not develop, manufacture, distribute, price, advertise or promote any Subject Products. However, “but for” Contractor Defendants’ actions in coordinating with J&J Defendants to remove only select Subject Products from select retail outlets, J&J would have been forced to make a full-blown, public recall and to properly inform consumers that their Subject Products were unsafe and defective. Furthermore, Contractor Defendants do not claim to have removed each and every recalled Subject Product, nor can they claim that their removal of Subject Products from select retail outlets prevented those Plaintiffs who had already purchased the products subject to the phantom recall from using them. Further, they can make no claim that they prevented any consumer from purchasing Subject Products from retail outlets not covered by the phantom recall.

The case of *Bennett v. Spear*, 520 U.S. 154, 169, 117 S.Ct. 1154, 1164, 137 L.Ed.2d 281 (1997) supports the conclusion that Plaintiffs’ injuries meet the traceability prong of the standing inquiry. *The Pitt News*, 215 F.3d at 361. In *Bennett*, the plaintiff sued one government agency, “Agency A,” which had coerced a second agency, “Agency B,” into enacting certain regulations that injured the plaintiff. *Id.* The court held that the plaintiff had standing to sue “Agency A,” even though it did not actually enact the regulations at issue. *Id.* The rationale was that the plaintiff’s injuries were directly traceable to the actions of “Agency A,” because “Agency B” would not have enacted the challenged regulation “but for” the actions of “Agency A.” *Id.* Following this logic, Plaintiffs’ injuries here are fairly traceable to the acts of the Contractor Defendants because, but for their involvement in conducting the limited and secretive phantom

recall, J&J Defendants would have been forced to publicly disclose the defective nature of their Subject Products and would have issued a broader recall, inuring to the benefit of all consumers in the Class.

As is required for standing to bring suit under Article III, Plaintiffs have suffered an injury in fact which was caused by Defendants' conduct and should therefore be permitted to invoke the jurisdiction of this Court.

**C. Plaintiffs' Amended Complaint Satisfies the Pleading Standards of Rule 8 and, Where Applicable, Rule 9(b).**

Fed. R. Civ. P. 8(a)(2) sets out the general rule for pleadings. A pleading that sets forth a claim must contain "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). Rule 8 "contemplates the statement of circumstances, occurrences, and events in support of the claim presented and does not authorize a pleader's bare averment that he wants relief and is entitled to it." *Jones v. Select Portfolio Servicing, Inc.*, 2008 WL 1820935 (E.D.Pa. May 21, 2007) (*quoting Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 556, n. 3, 127 S.Ct. 1955, 1965 n. 3, 167 L.Ed.2d 929 (2007) (*quoting* 5 Wright & Miller, FEDERAL PRACTICE AND PROCEDURE § 1202, 94-95 (3d ed.2004))). To meet the requisite standards, the complaint must "at least contain a modicum of factual specificity, identifying the defendants and the particular conduct of the defendants purported to have harmed the plaintiff." *Id.* (*quoting Nash v. Shannon*, Civ. A. No. 07-160, 2007 WL 1366778 at \*2 (M.D.Pa. May 7, 2007)). Each allegation must be simple, concise, and direct. *Id.* Plaintiffs have satisfied the pleading standards of Rule 8 in their claims against both J&J and Contractor Defendants.

Plaintiffs' claims against both the J&J and Contractor Defendants which sound in fraud are pled with the requisite particularity required by Fed. R. Civ. P 9(b). The heightened pleading standard of Fed. R. Civ. P 9(b) requires that "in all averments of fraud or mistake, the

circumstances constituting fraud or mistake shall be stated with particularity.” Rule 9(b) “requires plaintiffs to plead ‘the who, what, when, where, and how: the first paragraph of any newspaper story.’ ” *Kolar v. Preferred Real Estate Investments, Inc.*, 2008 WL 2552860 (E.D.Pa. June 19, 2008) (*quoting In re Advanta Corp. Sec. Litig.*, 180 F.3d 525, 534 (3d Cir.1999)(*quoting DiLeo v. Ernst & Young*, 901 F.2d 624, 627 (7th Cir.1990)). Plaintiffs need not, however, “plead the ‘date, place or time’ of the fraud, so long as they use an ‘alternative means of injecting precision and some measure of substantiation into their allegations of fraud.’” *Id.* (*quoting Rolo v. City Investing Co. Liquidating Trust*, 155 F.3d 644, 658 (3d.Cir.1998) (*citing Seville Indus. Machinery*, 742 F.2d 786, 791(3d.Cir.1984)).

**1. The Bulk of Plaintiffs’ Causes of Action Do Not Sound in Fraud, Therefore Making the Particularity Requirement of Fed.R.Civ.P. 9(b) Largely Inapplicable.**

Defendants wrongly assert that to survive a motion to dismiss the CAC must meet the heightened standards relevant to allegations of fraud. J&J Mem. at 16. While the CAC alleges fraud in one of eleven counts, at its core it alleges statutory consumer fraud and other non-fraud based causes of action. Therefore, the heightened pleading standards of Fed.R.Civ.Proc. 9(b) do not apply to the bulk of the claims in this case.<sup>12</sup> Plaintiffs’ CAC meets the requirements of Rule 8. Plaintiffs do not simply state that they “want relief and are entitled to it.” Instead, J&J and Contractor Defendants are given fair notice of the claim and grounds upon which the claims rest. *See Victory Outreach Center v. Meslo*, 2002 WL 1560242 at \*1 (E.D.Pa. July 1, 2002) (“the Federal Rules of Civil Procedure generally do not require detailed pleading of the facts on which

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<sup>12</sup> The law is clear that claims brought pursuant to statutory consumer fraud laws of the States in which Plaintiffs reside do not require pleading with particularity pursuant to Federal Rule 9(b). *See, e.g., Vassalotti v. Wells Fargo Bank, N.A.*, 732 F.Supp.2d 503, 510 (E.D.Pa. Aug.9, 2010); *Fingles v. Continental Cas. Co.*, 2010 WL 1718289, at \*7 (E.D.Pa. Apr. 28, 2010); *Seldon v. Home Loan Svcs.*, 647 F.Supp.2d at 451, 468-71 (ED.Pa. Aug. 4, 2009); *Flores v. Shapiro & Kreisman*, 246 F.Supp.2d 427, 432 (E.D.Pa. Oct. 29, 2002).

a claim is based. Instead, all that is required is a short and plain statement of the claim showing that the pleader is entitled to relief, enough to give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests”).

Plaintiffs allege that as a result of J&J and Contractor Defendants' unlawful conduct, and their scheme and conspiracy to suppress the truth about Subject Products, they suffered actual damages. Plaintiffs set forth in painstaking detail in the CAC the numerous recalls conducted by J&J Defendants. Plaintiffs incorporate the facts regarding numerous FDA warnings and Congressional investigations and hearings that occurred before and after the recalls of Subject Products. Under liberal notice pleading standards, Plaintiffs' allegations should suffice to allow Plaintiffs' claims to survive the instant Motions to Dismiss.

Even were this Court were to scrutinize the CAC under the heightened pleading standard of Rule 9(b), the detailed CAC here would meet such standard. As noted above, Plaintiffs have set forth the who, what, where and when regarding the unlawful conduct and omissions by the J&J and Contractor Defendants.

Plaintiffs' CAC sets forth in detail how Plaintiffs and the Class were defrauded by the acts and failures to act by the J&J and Contractor Defendants. In fact, paragraphs 126 through 245 of the “Factual Allegations” portion of Plaintiffs' CAC details facts as to the J&J and Contractor Defendants' knowledge, since 2002, of the deteriorating quality control at J&J Defendants' manufacturing plants. These averments detail how, despite J&J Defendants' knowledge of its degrading quality control leading to the manufacture and sale of defective products, quality control management ordered that these products be passed despite failing quality standard tests, in clear violation of FDA protocol. They show how the J&J and Contractor Defendants were involved in a fraudulent scheme, a description of their respective

fraudulent misrepresentations and omissions to Plaintiffs and consumers who purchased these products, the relevant timeframe as to when the fraudulent conduct was committed by J&J and Contractor Defendants, and the locations where the misrepresentations and omissions were said to have occurred. Furthermore, Plaintiffs describe each product recall issued by J&J Defendants, along with the specific products involved. The several FDA warnings and meetings with J&J Defendants (showing their awareness of adverse events being reported with regards to the defective products and intent in choosing not to disclose those defects to Plaintiffs) are also detailed. Finally, Plaintiffs' CAC recites the details of the scheme between J&J and Contractor Defendants to "secretly" remove certain Subject Products from select retail outlets without issuing a formal public recall, allowing consumers to continue to purchase and consume these products outside those select areas.

By pleading in detail the fraudulent scheme and conspiracy to conceal the truth involving both the J&J and Contractor Defendants, Plaintiffs have met the heightened pleading requirement under Rule 9(b).

## **2. Plaintiffs' Allegations State Claims for Relief Under the *Twombly* Standard.**

Plaintiffs' allegations in their CAC state various claims for relief which easily satisfy the pleading standards set forth in *Bell Atlantic v. Twombly*, 550 U.S. 544 (2007) and *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), to the extent these cases apply herein.

Under Federal Rule 8(a)(2), a complaint must contain a "short and plain statement of the claim showing that the pleader is entitled to relief." *Iqbal*, 129 S.Ct. at 1940. "[D]etailed factual allegations" are not required, *id.* (citing *Twombly*, 550 U.S. at 555) but the Rule does call for sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Id.* (citing *Twombly*, 550 U.S. at 570). A claim has facial plausibility when the pled factual

content allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged. *Id.* (citing *Twombly*, 550 U.S. at 556).

Two working principles underlie the *Twombly* case. First, the tenet that a court must accept a complaint's allegations as true is inapplicable to **threadbare recitals** of a cause of action's elements, supported by mere conclusory statements. *Id.* (citing *Twombly*, 550 U.S. at 555). Second, determining whether a complaint states a plausible claim is context-specific, requiring the reviewing court to **draw on its experience and common sense**. *Id.* (citing *Twombly* 550 U.S. at 556). A court considering a motion to dismiss may begin by identifying allegations that, because they are mere conclusions, are not entitled to the assumption of truth. *Iqbal*, 129 S.Ct. at 1940. While legal conclusions can provide the complaint's framework, they must be supported by factual allegations. *Id.* When there are well pled factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement to relief. *Id.*

The Plaintiffs' CAC at bar includes well pled factual allegations regarding the unlawful conduct of all of the Defendants, including the fraudulent scheme and conspiracy that existed between J&J and Contractor Defendants to conceal the truth concerning the defective products Plaintiffs and the Class purchased. While Contractor Defendants have resorted to counting the number of paragraphs wherein they are mentioned in the CAC in support of their arguments for dismissal under *Twombly* and *Iqbal*, nowhere do these precedents lend credence to such a claim that volume overrides substance in determining whether Plaintiffs' have pled "sufficient factual matter to state a claim to relief that is plausible on its face." Instead, the CAC asserts that, beginning in at least 2009, Contractor Defendants were engaged by the J&J Defendants to assist them in trying to secretly remove from the shelves of select major retailers the same defective

products that Plaintiffs ultimately purchased and either ingested themselves or gave to their young, sick children to ingest. At the time the Contractor Defendants were so engaged to conduct “market assessments” and “secret recalls,” its highest corporate officers – up to its President and CEO, Sean Davoren -- were fully aware of J&J Defendants’ manufacturing problems and quality control issues. Consequently, the Contractor Defendants’ “paragraph-counting” approach to the pleading standards of *Twombly* must yield to the reality that virtually every factual allegation relates to the overall scheme in which they were integrally involved: the misrepresentation and suppression of critical information about Subject Products so that J&J could continue to sell Subject Products to unwitting consumers at unreasonably high, premium prices in relation to their severely degraded value and sub-standard quality and condition.

#### **D. Plaintiffs’ Allege Sufficient Claims Under the Applicable Pleading Standards**

As discussed herein, Plaintiffs allege they suffered injuries in the form of the purchase of defective and worthless merchandise. *See* CAC ¶¶ 1, 12-19, 246; *see also*, discussion *supra*. Since Plaintiffs have alleged violations of consumer product safety rules their claims should not be dismissed. Nonetheless, Defendants ignore these allegations and argue that there are no allegations of “actual injury” caused by its conduct. J&J Mem. at 20-23. To show an injury in fact, the plaintiff need only allege an injury that is “concrete and particularized” and actual or imminent. *See Friends of the Earth, Inc. v. Laidlaw Env'tl. Servs., Inc.*, 528 U.S. 167, 180-181, 120 S.Ct. 693, 145 L.Ed 2d 610 (2000). Rather than address the actual injury from the loss of the purchase price for the defective product, Defendants simply quote the relevant state consumer statutes.

The injury suffered by the Plaintiffs, which forms the basis for other causes of action such as warranty, provides the Plaintiffs with standing to bring the state law consumer protection



claims. For instance, Plaintiffs' breach of warranty claims (discussed below), provide that, in addition to general damages naturally flowing from the breach of warranty, Plaintiffs may also recover incidental damages actually resulting from the breach, including expenses reasonably incurred in inspection, receipt, transportation, care, and custody of goods rightfully rejected, as well as any other reasonable expenses incident to the breach. *See* U.C.C. §2-715(1) & cmt. 1.

While commercial parties can enter into a contract of sale that would provide remedies for breach of warranty (either express or implied) that would be limited to repair or replacement of the nonconforming goods by the seller, for other parties, like consumers, such additional or substituted remedies will be construed to be *optional* unless they are expressly agreed by the parties to be exclusive. U.C.C. §2-719(1); *see, e.g., Massey-Ferguson Inc v. Laird*, 432 So.2d 1259, 1264 (Ala. 1983); *Hibbs v. Jeep Corp.*, 666 S.W.2d 792, 797 (Mo. Ct. App. 1984).

Here, the parties entered into no such contract that would in any way limit Plaintiffs' potential recovery to substituted recall remedies at Defendants' sole discretion. Rather, under the UCC, Plaintiffs should be entitled to receive a refund for the full purchase price of the products. The standard measure of damages in a breach of warranty action (whether express or implied) is the difference at the time and place of acceptance between the value of the goods accepted and the value they would have had if they had been as warranted, unless special circumstances show proximate damages of a different amount. U.C.C. §2-714(2). Consequently, damages determined by the "difference in value" formula will ordinarily be recoverable in an action for economic loss resulting from the breach of an express warranty. *See, e.g., 6000 S Corp. v. Kelly Energy Sys., Inc.*, No. C95-1804VRW, 1996 U.S. Dist. LEXIS 15205, at \*9 (N.D. Cal. Sept. 13, 1996); *Consolidated Data Terminals v. Applied Digital Data Sys. Inc.*, 708 F.2d 385 (9th Cir.1983); *Custom Automated Machinery v. Penda Corp.*, 537 F. Supp. 77 (N.D. Ill.

1982); *Mann v. Weyerhaeuser Co.*, 703 F.2d 272 (8th Cir. 1983); *Massey- Ferguson Inc. v. Laird*, 432 So.2d 1259 (Ala. 1983). This is also the standard measure of damages in an action to recover for economic loss resulting from a breach of an implied warranty of merchantability. *See, e.g., AFA Corp. v. Phoenix Closures Inc.*, 501 F. Supp. 224 (N.D. Ill. Jan. 20, 1980); *Burrus v. Itek Corp.*, 46 Ill. App. 3d 350, 4 Ill. Dec. 793, 360 N.E.2d 1168 (1977); *Vintage Homes Inc. v. Coldiron*, 585 S.W.2d 886 (Tex. Civ. App. 1979). In this case, Plaintiffs are entitled to a refund of the full purchase price of their worthless Subject Products after J&J Defendants issued recalls, as well as the taxes associated with such purchases. Such damage suffered by Plaintiffs provides them with standing to bring the state law consumer claims in addition to other claims.

**1. Plaintiffs' Allegations of Actual Injury Under the Relevant Consumer Protection Statutes of Their Home States Is Sufficient.**

As set forth above, Plaintiffs allege they suffered actual injury in fact from their purchases of defective, degraded and sub-standard Subject Products. *See* CAC at ¶¶ 1, 12-19, 246. Since Plaintiffs otherwise have alleged all the requisite elements for violations of consumer protection laws of the various states, as J&J Defendants' concede by implication,<sup>13</sup> Plaintiffs' consumer fraud claims should not be dismissed. Ignoring these well-pleaded allegations, Defendants urge there are no allegations of "actual injury" caused by their conduct. J&J Mem. at 20-23.

As set forth above, to show an injury in fact, the plaintiff need only allege an injury that is "concrete and particularized" and actual or imminent. *See Friends of the Earth, Inc.* 528 U.S. at 180-181. Rather than address the Plaintiffs' claims of actual injury from the loss of the

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<sup>13</sup> J&J Defendants' challenge to Plaintiffs' consumer fraud claims is limited to repeating their claim that Plaintiffs "fail() to allege actual injury" as set forth in their opening argument. Consequently, J&J Defendants concede that Plaintiffs have otherwise met the requirements for pleading the elements of violations of the various consumer protection laws of Plaintiffs' home states.

purchase price for the defective Subject Products, Defendants simply quote legal authorities concerning the relevant consumer statutes showing that some claim of loss must be made. Since Plaintiffs' allege such a loss, the pleading requisites for consumer fraud have been satisfied.<sup>14</sup>

## **2. The Standards for Claims Under Other States' Consumer Fraud Laws Have Been Met.**

While Contractor Defendants raise a concern, J&J Defendants and Plaintiffs agree that the issue of whether Plaintiffs can recover as representatives of a nationwide Class of patients that reside in States outside the Plaintiffs' states of residence is a matter best left for the class certification stage of these proceedings.<sup>15</sup> Plaintiffs disagree with Contractor Defendants that dismissal of the rights of absent Class members under the laws of such other States is either warranted or proper at this juncture. The matter is best deferred to another day.

## **3. Plaintiffs' Have Adequately Pled Their Federal RICO Claims.**

Plaintiffs have sufficiently and adequately pled their federal RICO claims. In attacking Plaintiffs' RICO claims, the J&J Defendants have argued that the Plaintiffs' CAC fails to allege

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<sup>14</sup> J&J Defendants reference "numerous other reasons why Plaintiffs fail to state viable claims under the various state consumer protection statutes," but wisely concede that these issues only become important at the class certification stage. J&J Mem. at 23 n. 18. Contractor Defendants do not agree that these issues are properly deferred, which is why Plaintiffs must address them here.

<sup>15</sup> See *Sheet Metal Workers Nat. Fund v. Amgen Inc.*, No. 07-5295, 2008 WL 3833577, at \*9 (D.N.J. Aug. 13, 2008)(refusing to address argument that plaintiff lacks standing to bring claims under the laws of states in which plaintiff failed to allege an injury, and explaining that "because class certification creates the jurisdictional issue, the Court must treat the statutory standing issue before it deals with Article III standing, as instructed by *Ortiz*")(citing *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 119 S.Ct. 2295 (1999)); *Clark v. McDonald's Corp.*, 213 F.R.D. 198, 204 (D.N.J. Mar. 3, 2003)(considering it appropriate to decide class certification before resolving Article III standing challenges where defendant had challenged plaintiff's "standing to assert claims on behalf of class members regarding restaurants that [plaintiff] has not visited, or in states [plaintiff] has not visited".); *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 363, 377 (S.D.N.Y. Feb. 14, 2002)(same); see also, *In re Pharmaceutical Industry Average Wholesale Price Litig.*, 233 F.R.D. 229 (D.Mass. Jan. 30, 2006)(in a nationwide consumer class action case brought against J&J and other drug companies, the MDL Court certified a near-nationwide class of consumers against J&J with only representative plaintiffs from two States).

an actual injury (as set forth above) and that it has not met RICO's purportedly strict pleading requirements. To the contrary, the CAC outlines a series of factual allegations that rigorously describe the Defendants' associations-in-fact, their scheme of fraud, the racketeering activity undertaken in furtherance of that scheme, and the actual injuries suffered by the Plaintiffs as a result of that activity. CAC ¶¶ 68 through 245. The Supreme Court directs that RICO's statutory language is to be read broadly; it must "be liberally construed to effectuate its remedial purposes." *See Sedima, S.P.R.L. v. Imprex Co., Inc.*, 473 U.S. 479, 497-98 (1985) (quoting Pub.L. 91-452, § 904(a), 84 Stat. 947).

**a. Plaintiffs Allege Actual Injury Under RICO.**

RICO requires that Plaintiffs plead injury in "business or property by reason of violation of section 1962." 18 U.S.C. §1964(c). A compensable injury "will flow from the commissions of the predicate acts." *Sedima, S.P.R.L. v. Imprex Co., Inc.*, 473 U.S. 479, 497-98 (1985). "RICO is to be read broadly" and "liberally construed to effectuate its remedial purposes." *Id.* Where Plaintiffs allege pharmaceutical products are in some way ineffective, courts find plaintiffs have plead an actual injury. *See In re Neurontin Marketing, Sales and Practices Products*, 433 F.Supp 172, 185-86 (D. Mass. 2006) (wherein plaintiffs could not proceed on a theory of overpayment for an unproven drug, but could proceed where they alleged the Subject Products were ineffective at the marketed dosages).<sup>16</sup> Courts have looked for allegations of suffering a medical injury, receiving inferior care, negligence, and/or breach of contract in determining whether a plaintiff has pled an actual injury under RICO. *See Maio v. Aetna, Inc.*, 221 F.3d 472, 485 (3d Cir. 2000). In the context of pharmaceuticals, Plaintiffs should allege that

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<sup>16</sup> J&J Defendants' cited cases at pages 13-14 of their Memo are in full accord with this proposition. According to J&J Defendants' parenthetical references, these cases all stand for the proposition that if the drugs at issue are unsafe, ineffective or otherwise defective, as alleged here, Plaintiffs have causes of action under various theories of liability, including RICO and consumer protection.

the Subject Products are “either unsafe, ineffective or somehow worth less than the price paid for the drug.” *See In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 2009 WL 2043604 at \*12 (D.N.J. 2009).

Plaintiffs here have satisfied this standard. Plaintiffs have alleged specific facts that demonstrate the Subject Products are unsafe, ineffective or otherwise worth less than the prices they paid. Reports issued by the FDA indicate a wholesale breakdown of quality control procedures at McNeil such that batches of the Subject Products distributed in the market contained “known contaminations” including gram-negative organisms. CAC ¶¶202-205. Furthermore, some batches were improperly dosed resulting in “super potent batches” while other products were sold without proper procedures to assure correct weight and measurements. *Id.* These allegations are just a few examples of those contained in the CAC which outlines a long list of quality control failures leading to the manufacture of products that were “unsafe, ineffective or somehow worth less than the price(s) paid” by consumers. *See In re Schering-Plough Corp.*, 2009 WL 2043604 at \*12.

**b. Plaintiffs Have Satisfied RICO’s Pleading Requirements.**

Plaintiffs have sufficiently and adequately pled the necessary elements to satisfy RICO’s pleading requirements.

**i. Plaintiffs Have Alleged a Viable RICO Enterprise.**

The Supreme Court provides the standard wherein an enterprise should have the following three structural features in terms of RICO: (1) a purpose, (2) relationships among those associated with the enterprise, and (3) longevity sufficient to permit these associates to pursue the enterprise’s purpose. *Boyle v. U.S.*, 129 S. Ct. 2237, 2244 (2009). The Court of Appeals for

the Third Circuit follows this standard, deeming it “relatively undemanding.” *See In re Ins. Brokerages Antitrust Litig.*, 618 F.3d 300, 374 (3d Cir.2010).

An enterprise “purpose” has simply the “meaning of the term in ordinary usage,” that is, “a common interest.” *Id.* An association-in-fact enterprise is a group of persons associated together for a common purpose of engaging in a course of conduct. *Id.* at 2243. Although evidence of a course of conduct does not necessarily establish an enterprise with a common purpose, the evidence to establish an enterprise with a common purpose may coalesce with proof of racketeering activity. *See U.S. v. Turkette*, 452 U.S. 576, 583, 101 S.Ct. 2524, 2528-2529 (1981).

In their CAC, Plaintiffs have alleged the facts sufficient to demonstrate a common purpose and common interest. Each Defendant intended that the various enterprises involved in this scheme give false and misleading statements to the members of the class and suppress material information. CAC ¶450. All of the Defendants were aware of this scheme to defraud the public and were knowing and willing participants. CAC ¶¶442, 448. The common purpose arises out of evidence for perpetuating the pattern of racketeering activity for which each Defendant played a specific and definite role. CAC ¶¶53-67, 437.

The second feature, the relationships among those associated with the enterprise, need not establish an organization with any particular nature. *Boyle v. U.S.*, 129 S. Ct. 2237, 2245 (2009). The group may be “informal” and “not much structure is needed”. *Id.* (internal quotations omitted). While a structure may have a hierarchy, chain of command, membership requirements, internal discipline mechanism, regular meetings, etc., there is no basis in RICO requiring a showing of such factors. *See id.* “Members of the group need not have fixed roles; different members may perform different roles at different times.” *Id.* The Defendants cite one case

suggesting that “the fact that the defendants played particular roles and were aware of each other’s actions does not show a decision-making structure.” *In re Am. Investors Life Ins. Co. Annuity Mktg. & Sales Practices Litig.*, 2006 WL 1531152 at \*7-8 (E.D.Pa. June 2, 2006). However, that case was decided before the definitive decision in *Boyle*, wherein the U.S. Supreme Court set out a “relatively undemanding” standard for showing a viable RICO enterprise. *In re Ins. Brokerages Antitrust Litig.*, 618 F.3d 300, 374 (3d Cir.2010). J&J Defendants’ failure to cite *Boyle* is telling, as they chose to adhere to a potentially outdated precedent in the clear face of the broader scope of association-in-fact enterprises introduced by *Boyle*.<sup>17</sup>

The CAC outlines the specific relationship among each Defendant associated with the enterprise. CAC ¶¶53-67. For example, Johnson & Johnson was responsible for the sale, marketing, and, through McNeil, the manufacture of the Subject Products. CAC ¶54. William C. Weldon, the current Chairman and Chief Executive Officer of Johnson & Johnson, and one of several responsible persons identified within the CAC, was responsible for the decisions that led to the breakdown in quality control at McNeil. Inmar, Inc.’s normal business operations include the processing and management of pharmaceutical products, but in this case Inmar was hired by Johnson & Johnson and/or McNeil to conduct a “phantom recall” of some of the Subject Products. CAC ¶63. The above examples are just a few allegations that clearly indicate that the CAC outlines in detail the positions and involvement of the Defendants associated with the enterprise. Under the standards set by the Court in *Boyle*, no other structural requirements are necessary. *See Boyle*, 129 S. Ct. at 2245.

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<sup>17</sup>Contractor Defendants do acknowledge the three features introduced by *Boyle* to successfully plead a viable RICO entity, but then claim in a conclusory fashion that Plaintiffs “do not sufficiently allege these three structural features with respect to any” of the enterprises identified in the CAC.

Finally, the third feature of a viable association-in-fact enterprise is longevity. The Supreme Court chose not to explore longevity in great detail. Instead, longevity must merely be “sufficient to permit [the] associations to pursue the enterprise’s purpose.” *Id.* at 2244. An enterprise needs only enough longevity to prove “that the enterprise had ‘affairs’ of sufficient duration to permit [it] to ‘participate’ in those affairs through ‘a pattern of racketeering activity.’” *Id.* “While the group must function as a continuing unit and remain in existence long enough to pursue a course of conduct, nothing in RICO exempts an enterprise whose associates engage in spurts of activity punctuated by periods of quiescence.” *Id.* at 2245. The J&J and individual Defendants’ engagement with the Contractor Defendants to participate in the “phantom recall” and the discussions, emails, and correspondence regarding same and as alleged in the CAC constitute the longevity intended by the standard. Moreover, the previously described email chain at Exhibit A makes it clear that the Defendants had an ongoing relationship over more than several months and more than one “phantom recall.” The Defendants incorrectly attempt to tie longevity to an exacting time period necessary to establish a pattern of racketeering activity, but cite no precedent supporting that methodology. However, the Supreme Court’s most recent pronouncement of the law in *Boyle* should be taken at face value, and longevity need only last long enough to permit participation in the alleged pattern of racketeering activity. *See id.*

Furthermore, Plaintiffs have repeatedly demonstrated that longevity in the CAC. The breakdown in quality control procedures at Johnson & Johnson and McNeil has been occurring since 2002, when repeated layoff’s weakened McNeil’s quality control department. CAC ¶129. Those quality control personnel that remained were, at least on one occasion, intimidated into passing products that violated FDA standards. CAC ¶134. Quality control had become so



ineffective that McNeil employees began to call the quality control team the “EZ Pass system.” CAC ¶130. The FDA issued reports in 2004 and 2010 citing poor quality control procedures at McNeil. CAC ¶¶131, 202, & 204. The CAC has demonstrated a long history of FDA violations and manufacturing and distributing unsafe or ineffective products to consumers. This history more than adequately establishes the associations-in-fact had the longevity to effectuate their purposes.

**ii. Plaintiffs Have Alleged that the Defendants “Conducted and Participated” in Enterprise Affairs.**

Plaintiffs have alleged that each defendant has “participated in the operation or management of the enterprise itself.” *Reves v. Ernst & Young*, 507 U.S. 170, 183 (1993). There “must be a nexus between the person and the conduct in the affairs of an enterprise.” *Clark v. Conahan*, 737 F. Supp. 2d 239, 269-70 (M.D.Pa. 2010) (*quoting University of Maryland at Baltimore v. Peat, Markwic, Main & Co.*, 996 F.2d 1534, 1539 (3rd Cir.1993)). However, RICO is not limited to managerial decisions; participants that act to “further the illegal aims of the enterprise by carrying out the directives of those in control” are also liable. *Freedom Med. Inc. v. Gillespie*, 634 F.Supp.2d 490, 506, 507 (E.D.Pa. 2007). A court should consider the nexus between the defendant and the conduct of the enterprise in order to determine if a particular defendant conducted or participated in enterprise affairs. *See id.* at 507, 508.

As discussed above, the CAC outlines specifically the involvement of each of the Defendants with the RICO enterprise. The allegations are not merely that the Defendants were “integrally involved” or “aware of” the scheme; rather, the CAC explains how Defendants were also responsible for making the decisions in furtherance of the racketeering activity. CAC ¶¶53-67. The Defendants’ specific positions and functions were explicitly detailed, and their very positions inform the kind of conduct and participation of each Defendant. Finally, when the

exact “scope and counters” of a defendant’s relationship with an enterprise is in question, courts should avoid making a determination at the motion to dismiss stage because they would not have the benefit of a fully developed factual record. *See Clark v. Conahan*, 737 F. Supp. 2d at 270.

**iii. Plaintiffs Have Alleged that the Defendants Participated in an Enterprise “Through a Pattern of Racketeering Activity.”**

Plaintiffs have sufficiently and adequately alleged that the Defendants participated in an enterprise “through a pattern of racketeering activity”.

**(1) Plaintiffs Have Alleged Two Predicate Acts.**

Plaintiffs have sufficiently alleged predicate acts of wire and mail fraud, making their RICO claims plausible and meritorious. Under RICO, predicate acts of wire and mail fraud include the following elements: a scheme to defraud, use of the telephone or mail to conduct the scheme, and an intent to conduct a fraudulent scheme. *See United States v. Hannigan*, 27 F.3d 890, 892 (3rd Cir.1994). Courts also tend to require that plaintiffs allege a reliance on the fraudulent scheme. *See Baker v. Fam. Credit Counseling Corp.*, 440 F.Supp.2d 392, 410 (E.D. Pa. July 28, 2006). But, where plaintiffs reasonably relied upon representations made by the defendants, and allege that those representations induced, enticed, or show an action in conformity with reliance, then the plaintiffs have successfully alleged reliance. *See id.* at 411.

When alleging mail or wire fraud, the plaintiffs need not show that the fraud was an essential part of the scheme. *See Levine v. First Am. Title Ins. Co.*, 682 F.Supp.2d 442, 465 (E.D. Pa. Jan. 14, 2010). Rather, the mail or wire fraud need only be a part of or “incident to the essential part of the scheme.” *See id.* The fraudulent statements “need not be false or fraudulent on their face, and the accused need not misrepresent any fact, since all that is necessary is that the scheme be reasonably calculated to deceive...” an ordinarily prudent person. *See Id.* at 462. “Group pleading” is only impermissible in so far as the involvement of the defendants is unclear;

however, plaintiffs can successfully allege mail and wire fraud where they plead the conduct of each defendant. *See Gross v. Waywell*, 628 F.Supp.2d 475, 494-95 (S.D.N.Y. June 16, 2009).

The CAC demonstrates several areas of fraudulent statements or misrepresentations by the Defendants made in furtherance of their scheme. The Defendants' Motions to Dismiss targets only one such statement, a memorandum summarizing an order from Johnson & Johnson to WIS to initiate a phantom recall of one of the Subject Products. CAC Ex. E. This memorandum gives a specific timing to the request, the entity giving the order, and the entity performing the recall. *Id.* The memorandum also details the clandestine and deceptive methods used in this phantom recall in order to further the underlying scheme. *Id.* Furthermore, the Defendants shipped millions of bottles of the Subject Products, transaction invoices, and other communications respecting the Subject Products through the U.S. mail and wire to retailers across the country, despite knowing that the Subject Products were either unsafe or ineffective. CAC ¶461. Plaintiffs relied on Defendants' "reputation, experience, technical and scientific expertise, ability, and judgment," understanding that the products were safe because they were sold under the Johnson & Johnson brand. CAC ¶¶202-205, 496. Indeed, the CAC makes clear the Defendants traded on the formerly good name of McNeil in continuing to charge premium prices for products all Defendants knew were substandard, even dangerous.

Furthermore, the CAC contains "specific allegations as to which fraudulent tactics were used against" Plaintiffs. *Rolo*, 155 F.3d at 659. Plaintiffs need only "inject[ ] precision and some measure of substantiation" to plead viable fraud claims. *Seville Indus. Machinery Corp. v. Southmost Machinery Corp.*, 742 F.2d 786, 791 (3d Cir.1984). Defendants are indisputably on notice of the "precise misconduct" charged. These predicate act allegations suffice under RICO. The communications (memos, emails, facsimiles, etc.) discussing and outlining the process of

furthering the phantom recall, the actions involved with traveling to retail outlets and removing the items by the Contractor Defendants per the J&J Defendants' instructions, and the continued reliance by the Plaintiffs in the meantime on the reputation of the J&J Defendants and their products, demonstrates much more than two predicated acts of wire and mail fraud.

**(2) Plaintiffs Have Met the Continuity Requirement.**

Plaintiffs may demonstrate a pattern of racketeering activity through either open-ended or closed-ended continuity. *See H.J. Inc. v. Northwestern Bell Tel. Co.*, 492 U.S. 229, 241 (1989). A closed-ended continuity involves acts committed over a substantial period of time, tending to last several years. *See Hughes v. Consol-Pennsylvania Coal Co.*, 945 F.2d 594, 611 (3d Cir.1991). Although such schemes may last years, courts have found that a period as short as 14 months will satisfy closed-ended continuity. *See U.S. v. Pelullo*, 964 F.2d 193, 210 (3d Cir.1992). Several repeated acts over a shorter period of time, such as 10 months, may also satisfy the closed-ended continuity requirement. *See id.* (citing *Farberware, Inc. v. Groben*, 764 F. Supp. 296, 306 (S.D.N.Y. May 16, 1991)).

Johnson & Johnson and McNeil began to undermine the quality control processes at McNeil at least as early as 2002. CAC ¶¶129-130. The FDA began criticizing such lapses in quality control at least as of 2004. CAC ¶¶131-132. The shipping of more than one million defective bottles of St. Joseph's aspirin, an act similar to those alleged in the CAC, occurred in 2005. CAC ¶133. Even if these past, similar, and repeated acts were ignored, the Plaintiffs have alleged a substantial period of time for racketeering activity involving the Subject Products. Defects were first discovered in the Subject Products at least as early as 2008. CAC ¶458. The phantom recall of July 2009 began a round of successive recalls that lasted into December 2010 (and continue even today). CAC ¶¶145-153, 191. We now know by the letter written from

Congress to J&J CEO Bill Weldon that the Contractor Defendants were directly involved in the racketeering activity respecting children's Subject Products by at least summer 2009. *See* Ex. A hereto. FDA reports from April 30, 2010 and December 9, 2010, indicate that quality control failures remained uncorrected throughout this recall period. CAC ¶¶202, 204. The Plaintiffs alleged that the Defendants made deceptive statements during congressional hearings held on May 27, 2010. CAC ¶¶213-218. Even if, conservatively, the period of racketeering activity was estimated to begin in 2008, the CAC demonstrates continued racketeering activity up until at least December 2010, a period of at least two years. This more than adequately satisfies the requirements for closed-ended continuity.

Furthermore, the Plaintiffs have adequately alleged an ongoing enterprise existed to engage in a scheme of fraud. A plaintiff can satisfy the "continuity" prong of RICO analysis by demonstrating a continued threat of racketeering activity. *See Tabas v. Tabas*, 47 F.3d 1280, 1295 (3d Cir.1995). To establish a threat of continuity, a plaintiff can show that the predicate acts are part of an entity's ongoing means of doing business. *See Emcore Corp. v. PricewaterhouseCoopers, LLP*, 102 F. Supp. 2d 237, 253 (D.N.J. July 6, 2000).

Plaintiffs specifically allege an ongoing criminal enterprise or ongoing predicate acts in several parts of the CAC. CAC ¶¶5, 461, 521. Furthermore, the facts alleged demonstrate a scheme that has continued since 2002. CAC ¶¶129-130. The scheme has continued up to the time of the filing of initial complaints in this action, with another half-dozen recalls being issued since April 2010. This scheme undermined quality control procedures at McNeil such that unsafe or ineffective drugs were manufactured and distributed into the market, such as St. Joseph's aspirin and all of the Subject Products in this case. CAC ¶¶133,458. In that time period, the FDA has issued numerous reports and held numerous meetings with Johnson & Johnson

executives. CAC ¶¶192-209. The FDA continues to monitor changes in the J&J manufacturing facilities. Congress has held two hearings calling Johnson & Johnson's practices into question, and its investigation is still pending. CAC ¶¶210-223. Yet, as the December 2010 FDA report demonstrates, violations continue to occur. CAC ¶204. These facts demonstrate an ongoing threat of racketeering activity.

### **(3) Plaintiffs' Allegations Meet the Distinctiveness Requirement.**

The Defendants argue that the "Corporate Family Enterprise" and the "Misleading Marketing Enterprises" fail to meet the distinctiveness requirement. The "Corporate Family Enterprise" is an association-in-fact between Johnson & Johnson and McNeil. CAC ¶438. In support of their argument, the Defendants cite several cases, including *Brittingham v. Mobil Corp.*, 943 F. 2d 297, 302, 303 (3d Cir.1991), suggesting that these cases stand for the proposition that a parent corporation cannot join with their subsidiary to form an association-in-fact enterprise. These cases involved facts distinct from the present case. *See Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412-13 (3d Cir.1993) (parent company and subsidiary-defendant were not sufficiently distinct from enterprise-corporation because all three acted in concert); *Brittingham v. Mobil Corp.*, 943 F.2d 297, 303 (3d Cir.1991) (neither parent company nor subsidiary could be the RICO enterprise because both were named as defendants and agent-defendants merely carried out the directives of the corporate defendants).

Furthermore, courts in Pennsylvania have long recognized that the distinctness requirement may be met where the parent and subsidiary have played distinctly different roles in the racketeering activity. *See example, Lorenz v. CSX Corp.*, 1 F.3d 1406, 1412 (3d Cir. 1993). The Plaintiffs have pled adequate facts to show that Johnson & Johnson had a distinct role within the "Corporate Family Enterprise." McNeil was responsible for the actual manufacture and

shipping of the Subject Products, while Johnson & Johnson directed the Contractor Defendants to initiate the phantom recall and controlled other aspects of the concealment and suppression of information. Johnson & Johnson also controlled the timing and scope of product recalls, and the “refund” program. Johnson & Johnson and McNeil took separate roles in the quality control of the Subject Products, and each both took distinct actions to undermine these systems. McNeil and Johnson & Johnson made various separate but deceptive statements to the FDA and to Congress. While acting toward the same purpose in their scheme to defraud, each Defendant in the “Corporate Family Enterprise” maintained distinct and separate roles in the furtherance of the scheme.

The Defendants also have argued that the “Misleading Marketing Enterprises” fail to meet the distinctiveness requirements because a corporation cannot join with its individual agents to form a RICO enterprise. It is well recognized that an employee is a distinct person from the employer corporation. *See Cedric Kushner Promotions, Ltd. v. King*, 533 U.S. 158, 163 (2001). It is true that a corporation cannot join its officers in being both a person involved in an enterprise and the enterprise through which the racketeering scheme was perpetrated. *See Jaguar Cars, Inc. v. Royal Oaks Motor Car Co., Inc.*, 46 F.3d 258, 268 (3d Cir. 1995). However, such cases stand for the unremarkable proposition that a person must be distinct from the RICO enterprise conducted. The Plaintiffs have alleged sufficient facts to show that Johnson & Johnson was distinct from the enterprise formed by the corporation and its employees. First, there is not a single, but several, “Misleading Marketing Enterprises” which undertook separate roles in perpetuating the common scheme to defraud. CAC ¶446. Second, Johnson & Johnson is a part of several other RICO enterprises, including the “Corporate Family Enterprise” and the “Contractor Enterprises,” and in each of those enterprises, Johnson & Johnson undertook distinct

and separate acts. CAC ¶438. Finally, Johnson & Johnson as a corporation engaged in activity that was separate and distinct from its individual officers, such as the cut backs in quality control at Johnson & Johnson which were separate and distinct acts from the misleading statements individuals made to Congress. CAC ¶¶137, 210-223. It is apparent from the factual allegations in this case that Johnson & Johnson was an individual person, as opposed to the RICO enterprise, that acted in several separate schemes with the common goal to defraud its customers.

**4. Plaintiffs' Claims for Breach of Implied Warranty of Merchantability and Fitness for a Particular Purpose Are Adequately Pled Under the Laws of Their Home States.**

Defendants assert that the Plaintiffs' breach of implied warranty claims fail, with respect to the Recalled Subject Products, because Defendants allegedly offered a "cash refund" and Plaintiffs cannot recover anything more by means of this litigation. Defendants are wrong. With respect to the broader group of Subject Products (of which Recalled Subject Products are a subset), Defendants assert that there is no allegation of performance failure and thus no breach of the implied warranty. Defendants are wrong again.

As an initial matter, Defendants have not provided the Court with the complete recitation of the law respecting damages for breach of an implied warranty under the Uniform Commercial Code ("UCC"). Indeed, Defendants claim that the measure of damages under the UCC, as adopted by state law, is a bright line rule restricted to the difference between "the value of the goods accepted and the value of the goods if they had been as warranted." *See* J&J Mem. at 37 (*citing to Polaris Indus., Inc. v. McDonald*, 119 S.W. 3d 331, 336-37 (Tex. App.-Tyler, 2003)(*citing* Tex. Bus. & Com. Code § 2-714(b)).

The correct general standard for the measure of damages in a breach of implied warranty action under the UCC is the difference at the time and place of acceptance between the value of



the goods accepted and the value they would have had if they had been as warranted, *unless special circumstances show proximate damages of a different amount*. Uniform Commercial Code § 2-714(2)(emphasis added); Tex. Bus. & Com. Code §2.714(b)(statutory remedy for the breach of the implied warranty of merchantability is direct damages, “unless special circumstances show proximate damages of a different amount.”); 13 Pa. Con. St. § 2714(b)(the measure of damages for breach of warranty under the UCC “is the difference . . . between the value of the goods accepted and the value they would have had if they had been as warranted unless special circumstances show proximate damages of a different amount); N.Y.U.C.C. § 2-714(2)(same).

This general standard is not the only standard in that there are other alternative measures of general damages depending on the circumstances. The most frequently employed alternative measure of a plaintiff's general damages is the price of replacement goods. *See, e.g., Duff v Bonner Building Supply Inc*, 103 Idaho 432, 649 P2d 391 (Idaho App.1982), *affd* 105 Idaho 123, 666 P2d 650 (1983). Damages determined in accordance with this formula may often be recovered where the defective character of the goods sold by the defendant renders them unusable. *See id.* (award of damages based on cost of replacement paneling was upheld where paneling purchased from defendant was useless and could not be salvaged). Alternative ways of measuring general damages may occasionally be used where the facts prevent application of the "difference in value" or "cost of replacement" formulas. *See, e.g., Mountaineer Contractors Inc v Mountain State Mack Inc*, 165 W.Va. 292, 268 SE2d 886 (W.Va.1980)(buyer of defective bulldozers recovered repair costs where neither determination of actual value nor replacement cost was possible due to unusual market factors).

As an initial matter, determination of the proper measure of damages under a breach of warranty claim is premature at the dismissal stage, since Plaintiffs have not had discovery (other than the miniscule 98 pages) or time to develop an appropriate damage model with experts. Further, even if the general standard were deemed applicable, the allegations in the CAC sufficiently allege special circumstances that would militate toward deviation from the general standard.

Notwithstanding the above damage standards, J&J Defendants erroneously assert in their Motion to Dismiss that their “cash refund” program provides complete relief to every consumer purchaser, for every purchase of a Recalled Subject Product, and that no other relief is available under a breach of implied warranty claim. The precise amount Defendants have been paying in the way of refunds, assuming they are actually paying refunds, and the circumstances and conditions by which these alleged refunds have been made, has yet to be determined and is a matter for future discovery in light of the identified deficiencies to date.

Plaintiffs’ CAC clearly alleges, *inter alia*, a failure on the Defendants part to make refunds, complete refunds, refunds for all purchases, and/or refunds that include all incidental expenses, including sales tax. *See* CAC. at ¶¶12, 14, 15, 16, 17, 231, 232, 233, 241-245. Indeed, Plaintiffs’ CAC alleges that Defendants are not making refunds for all Subject Products, and that with respect to the Recalled Subject Products, the refund program imposes numerous conditions on consumer eligibility preventing consumers from receiving even the full “refund” being offered for all their product purchases. *See* CAC at ¶¶ 10, 11, 18.

For instance, Plaintiffs have alleged that J&J requires absolute proof of purchase as a condition precedent with respect to the Recalled Subject Products. *See* CAC at ¶18. Plaintiffs have alleged that Defendants themselves instructed consumers to destroy and dispose of the

Recalled Subject Products, along with the packaging materials (that contained identifying numbers, National Drug Code numbers, lot numbers, expiration dates, and specific product names). *See* CAC at ¶¶ 13, 228, 229. Plaintiffs further allege that, only after instructing consumers to dispose of these materials, did J&J Defendants offer a “cash refund” provided consumers could supply the very information Defendants had instructed consumers to throw away. *See* CAC at ¶¶ 227-228. Plaintiffs alleged that J&J Defendants’ manipulations, instructions and conditions rendered it difficult (if not impossible) for consumers to meet J&J’s requisites for obtaining cash refund. *See* CAC at ¶¶ 227, 230, 233. On these facts, J&J Defendants can hardly contend that all consumers in the Class have been fully compensated.

Further, Plaintiffs have alleged that all Defendants engage in clandestine “phantom recalls” without providing public announcements, they deliberately delayed recalls, they issued recalls on top of prior recalls for the same products confusing customers,<sup>18</sup> they concealed and suppressed the defective condition and lack of quality of all Subject Products, all of which acts and omissions expressly, if not inferentially, demonstrate a failure on the part of J&J Defendants to provide complete relief to all consumers for all purchases of Subject and Recalled Subject Products. *See* CAC at ¶¶ 4, 5, 7, 8, 10, 11, 12, 63, 64, 66, 126-144, 145-191, 192-209, 236.

In addition, Defendants’ Motions to Dismiss fail to acknowledge Plaintiffs’ allegations that Defendants issued (and in fact aggressively favored) worthless coupons in lieu of full and

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<sup>18</sup> For example, on January 11 and March 29, 2011, J&J recalled various Benadryl, Sudafed, Tylenol 8 Hour, Tylenol Arthritis Pain, and Tylenol upper respiratory products that had been manufactured at McNeil’s Fort Washington plant nearly a year or more before they were recalled. That plant was closed in April 2010 because of, *inter alia*, severe quality control problems and ongoing violations of FDA rules and regulations. Defendants claim in their Motion to Dismiss that their refund program provides complete relief does not address in any way exactly how any consumer could possibly anticipate such delayed recalls or would have had the foresight to retain sufficient indicia of purchase to meet the conditions J&J has imposed with respect to their alleged refund program, notwithstanding Plaintiffs’ allegations of the deficiency of any such refunds.

complete cash refunds to all purchasers for all purchases of Subject Products. *See* CAC at ¶¶14, 15, 16, 233, 239, 241-245. Plaintiffs directly allege that the coupons were worthless in that they, *inter alia*, could not be used to replace defective product because there was simply no non-defective product available for purchase particularly given the complete shutdown and closure of McNeil’s Fort Washington, Pennsylvania, manufacturing facility. *See* CAC at ¶ 14. Further, the coupons have no cash value and are not transferrable, meaning they have no value in the eyes of a court reviewing them as fair compensation for consumer loss. Thus, Defendants’ assertions about the value of their refund program are undermined by the fact of their issuance of worthless coupons.

The courts have determined what “value” consists of with respect to coupons when offered as compensation for a claim of loss, as here in the case of J&J Defendants’ offer of a “refund” in the form of a “high value coupon” on the purchase of a future McNeil product. Indeed, the standard for coupon value was first developed in this circuit by the Third Circuit in its seminal decision in *In re General Motors Corporation Pick-Up Truck Fuel Tank Products Liability Litigation*, 55 F.3d 768 (3d Cir. 1995)(“*GM Trucks*”). That standard for coupon value was later codified in 28 U.S.C.A. § 1712, as part of the Federal Class Action Fairness Act (“CAFA”). Today, CAFA requires that before any court can approve a coupon settlement in a class action, the judge must hold a fairness hearing and make a written finding that the settlement is fair, reasonable, and adequate with respect to the coupons being offered. This provision echoes the requirements of Rule 23(e)(1)(C), while adding the requirement that the court’s finding as to the coupons be written. “Although the ‘fair, reasonable, and adequate’ language used in section 1712(e) is identical to the language relating to settlement approval contained in Fed. R. Civ. Pro. 23(e)(2), several courts have interpreted section 1712(e) as imposing a

heightened level of scrutiny in reviewing such [coupon] settlements.” *True v. American Honda Motor Co.*, 749 F.Supp.2d 1052, 1069 (C.D.Cal. Feb. 26, 2010).

In *GM Trucks*, as this Court is likely aware, consumer plaintiffs were offered a coupon redeemable for \$1,000.00 towards a future purchase of a GM truck. The Third Circuit noted that, “the fact that the settlement involves only non-cash relief, which is recognized as a *prime indicator of suspect settlements*, increases our sense that the class's interests were not adequately vindicated.” *Id.* at 803 (Emphasis supplied). The Court engaged in a lengthy analysis of the “value” of the coupons, when a defendant manufacturer attempts to settle a matter by simply offering coupons to injured class members in lieu of cash. The Court ultimately concluded that the proposed coupon settlement was not reasonable based in part on “the fact that the coupons provided no cash value” and that, even if the class members were “transferring the certificate within the household for full value or selling the certificate for \$500,” it was still an unreasonable and inadequate settlement because certain class members were “unable or unwilling to purchase another GM truck.” *Id.* at 807. Consequently, *GM Trucks* provided future courts with a reasonable benchmark for assessing the value of manufacturer coupons on future product purchases to resolve consumer class claims: such coupons should have actual cash value, should be transferrable and should not require the purchase of the product at issue in the lawsuit.

In the instant case, the “high value coupon” J&J Defendants have offered Class members provide no cash value, are not transferable and expressly require a future purchase of a McNeil product, something Class members are unlikely to want given McNeil’s horrendous history of quality control issues. As the Court in *GM Trucks* observed, “[e]ven where class members do manage to use the certificates, we are concerned about their *real value*. It may not be the case

that the certificates saved those class members \$1,000 on something they would have otherwise bought; those class members may only have purchased new GM trucks because they felt  *beholden* to use the certificates.” *Id.* at 808. (Emphasis added). Courts have consistently held that coupons “do not provide meaningful compensation to class members; they often fail to disgorge ill-gotten gains from the defendant; and they often require class members to do future business with the defendant in order to receive compensation.” *True v. American Honda Motor Co.*, 749 F.Supp.2d 1052, 1069 (C.D.Cal. Feb. 26, 2010)(citing *Figueroa v. Sharper Image Corp.*, 517 F.Supp.2d 1292, 1302 (S.D.Fla. Oct. 11, 2007)).

Because J&J Defendants hold out their “refund program” as the principle basis for challenging whether Plaintiffs and the Class in this case have suffered actual injury in fact, their program must be scrutinized by this Court on a fulsome record. Indeed, even without discovery, Plaintiffs have identified several deficiencies in the coupon portion of the refund program in that (1) J&J initially encouraged customer service representatives to steer consumers to coupons as the first (only) option, (2) the coupons are expressly conditioned on the purchase of a future product manufactured by McNeil, (3) McNeil is not making any products to day [and has not been for over a year], (3) the coupons have no cash value, and (4) they are not transferable. All of these deficiencies undermine J&J Defendants’ claims that the consumer Class members who received coupons in lieu of cash have been “fully compensated” for their losses alleged in this case.

Notwithstanding all of the above, Defendants’ assertions that Plaintiffs’ implied warranty claims fail because Defendants claim to have provided “cash refunds” to some but not all consumers is contradicted by the very authority Defendants urge the Court to consider in their Motion to Dismiss. Defendants cite to *Stearns v. Select Comfort Retail Corp.*, No. 07-2746,

2009 WL 1635931 at \* 5 (N.D.Cal. June 5, 2009) which holds that a plaintiff is not limited to a specified remedy if circumstances cause the particular remedy to “fail of its essential purpose.” Here, Plaintiffs have sufficiently alleged a failure on the part of Defendants to provide complete relief to all consumer purchasers.

In addition to the above, a plaintiff bringing claims for breach of the implied warranty of merchantability and fitness may recover incidental damages, including expenses reasonably incurred in inspection, receipt, transportation, and care and custody of goods rightfully rejected, as well as any other reasonable expenses incident to the breach. *See* Uniform Commercial Code § 2-715(1) and Official Comment 1. Indeed, Section 2-715(1) provides that:

(1) Incidental damages resulting from the seller's breach include expenses reasonably incurred in inspection, receipt, transportation and care and custody of goods rightfully rejected, any commercially reasonable charges, expenses or commissions in connection with effecting cover and any other reasonable expense incident to the delay or other breach.

Unif. Commercial Code § 2-715(1).

The description of incidental damages found in § 2-715(1) is not to be construed as limited or exhaustive to just those specified. Indeed, Note 1 to § 2-715 specifically states that:

Subsection (1) is intended to provide reimbursement for the buyer who incurs reasonable expenses in connection with the handling of rightfully rejected goods or goods whose acceptance may be justifiably revoked, or in connection with effecting cover where the breach of the contract lies in non-conformity or non-delivery of the goods. The incidental damages listed are not intended to be exhaustive but are merely illustrative of the typical kinds of incidental damage.

Thus, incidental damages can include all reasonable expenses the buyer incurred “in inspecting, shipping, handling and storing” the defective goods. *Consolidated Data Terminals v. Applied Digital Data Systems*, 708 F.2d 385, 393-94 (9th Cir.1983); *Carbontek Trading Co., Ltd. v. Phibro Energy, Inc.*, 910 F.2d 302, 307 (5<sup>th</sup> Cir.1990). Where the plaintiff elects to revoke acceptance of the goods and recover the purchase price, the plaintiff may recover as incidental

damages expenses reasonably incurred in returning the goods to the seller. *See e.g., AFA Corp v. Phoenix Closures Inc*, 501 F. Supp. 224 (N.D. Ill. Nov. 6, 1980)(purchaser of defective bottle cap liners recovered as incidental damages shipping and handling expenses incurred in returning goods).

Where the price of replacement goods is recovered as general damages, reasonable expenses arising from physical replacement of the goods may ordinarily be recovered as incidental damages. *See, e.g., Duff v Bonner Building Supply Inc*, 103 Idaho 432, 649 P2d 391 (Idaho App., 1982), *affd*, 105 Idaho 123, 666 P2d 650 (1983)(purchaser of defective paneling recovered as incidental damages cost of removing defective paneling and installing replacement paneling); *GFSI. Inc. v. J. Loong Trading, Ltd.*, 505 F. Supp. 2d 935 (D. Kan. Apr. 25, 2007)(Difference between cost of air and ocean freight to transport replacement garments by air freight after seller failed to deliver goods was recoverable as incidental damage).

Other expenses have also been allowed as incidental expenses. For example, in *Willred Co. v. Westmoreland Metal Mfg. Co.*, 200 F.Supp. 59, 66-67 (E.D.Pa. Oct. 4, 1961), the court found that the plaintiff could recover labor and travel costs incurred in conducting furniture repairs. *See also, Carbo Industries v. Becker Chevrolet*, 112 A.D.2d 336, 491 N.Y.S.2d 786, 790 (N.Y.App.Div.1985), *appeal dismissed*, 66 N.Y.2d 1035, 499 N.Y.S.2d 1030, 489 N.E.2d 1303 (1985)(towing costs and costs of diagnosing the problem were compensable incidental damages).

Here, Plaintiffs have expressly and impliedly pled the existence of incidental damages. *See* CAC at ¶ 12. These incidental damages include, *inter alia*, Plaintiffs' expenditure of time and resources to effect replacement or cover of the defective medicines, time and resources in disposal of defective products, transportation expenses to obtain replacement products<sup>19</sup>,

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<sup>19</sup> Recall that these medicines were for treatment of cold, flu, allergies and other ailments for which consumers likely would seek immediate replacement medicines.



including wear and tear on personal automobiles or other modes of transportation, mailing and/or shipping expenses to obtain replacement product or other expense incurred in effecting a replacement, such as payment of additional state sales taxes and other incidental expense.

The cost of obtaining replacement product is particularly noteworthy with respect to those consumers who received coupons for their purchases. As Plaintiffs have alleged, the coupons were worthless in that Class members could not utilize the coupons for replacement of the defective product (even to this day) because such product simply was not available for purchase. Thus, Plaintiffs have adequately alleged that Class members necessarily incurred incidental expenses, related to the breach and are recoverable under UCC § 2-715(1).

Finally, with respect to Subject Products not recalled, Defendants claim that Plaintiffs have only made a “naked assertion devoid of facts” in their assertion that such Subject Products were defective. Defendants are wrong. Plaintiffs’ CAC alleges, *inter alia*, Defendants had long running and ongoing quality control problems across all product lines, they engaged in suppression and concealment of those problems, continued producing defective products, continued to roll out a string of product recalls that continues today with alarming regularity, they engaged in flagrant violations of FDA rules and regulations, adverse FDA inspection reports have issued, particularly with regard to quality control, and Congress has convened investigations regarding same. *See* CAC at ¶¶ 1, 4, 5, 6, 8, 95-120, 126-142, 143-191, 192-209, 210-223. It is instructive that, while Defendants assert that Plaintiffs have failed to make sufficient allegations regarding the defective nature of the Subject Products, as time goes on, more and more Subject Products become Recalled Subject Products.<sup>20</sup>

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<sup>20</sup> Notably, since the time of the filing of the Consolidated Complaint, the J&J Defendants have instituted several additional recalls including two recalls that involved heretofore unrecalled Subject Products manufactured at McNeil’s Fort Washington manufacturing facility prior to that facilities closure. Thus, the J&J Defendants’ own actions, in particular the institution and/or

Defendants also claim that Plaintiffs, in order to sustain a claim for breach of an implied warranty with respect to Subject Products, must demonstrate an actual manifestation of the product's alleged defect. In support, Defendants cite to *Cardinal Health 301, Inc. v. Tyco Elecs. Corp.*, 169 Cal.App. 4<sup>th</sup> 116, 87 Cal Ptr.3d 5, 33 (2008).

However, the question is not whether there has been an external and observable manifestation of a defect with regard to the Subject Products. The question is more correctly stated as whether the Subject Products were defective at the time Defendants sold them, and thus, were unfit for their usual purpose and not merchantable. *See, e.g. Quality Air Services, LLC v. Milwaukee Valve Co., Inc.*, 671 F.Supp.2d 36, 45-46 (D.D.C. Nov. 25, 2009)(fact that an installed and still functioning valve had not failed was not the determinative issue of whether the valve contained a manufacturing defect that rendered it unfit for its intended use); *Tietsworth v. Sears*, 720 F. Supp 2d 1123, 1142 (N.D.Cal. Mar. 31, 2010)(“The mere manifestation of a defect by itself does not constitute a breach of the implied warranty of merchantability. Instead there must be a fundamental defect that renders the product unfit for its intended purpose”)(*quoting Stearns v. Select Comfort Retail Corp.*, No. 08-2746 JF, 2009 WL 1635913 at \*8 (N.D. Cal. June 5, 2009)).

Plaintiffs' CAC sufficiently alleges that Plaintiffs intended to purchase pure, unadulterated product of the quality and condition advertised. Plaintiffs have sufficiently alleged that what was sold to them by J&J Defendants were products that suffered from overarching manufacturing defects that rendered the Subject Products unfit for their ordinary purpose. Indeed, all of the Subject Products are alleged to have suffered from similar quality defects including, *inter alia*, particulate and chemical contamination, filth, super and sub potency issues.

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expansion of recalls involving heretofore unrecalled Subject Products, certainly suggests something more than naked assertions devoid of facts on the part of Plaintiffs.

Plaintiffs adequately allege that these defects resulted from significant quality control problems at J&J manufacturing facilities, especially at McNeil's Fort Washington manufacturing plant. These problems are evidenced by the numerous FDA violations and adverse reports, multiple, ongoing recalls, and multiple, ongoing failures in meeting cGMP standards making the Subject Products unfit for their intended purpose.

Thus, when considered in totality, Plaintiffs' allegations adequately allege facts that, if true, would support a claim for relief under a breach of implied warranty. Defendants' Motion to Dismiss with respect to these claims should be denied.

**5. Plaintiffs' Federal Magnuson-Moss Warranty Act Claims Are Adequately Pled.**

Defendants have moved the Court to dismiss Plaintiffs' Magnuson Moss Warranty Act ("MMWA") claims on the following grounds: (1) the implied warranty claims fail as the Plaintiffs are already entitled, in the absence of this litigation, to the maximum recovery allowed by law; (2) Plaintiffs have failed to meet the MMWA's jurisdictional requirements for class actions; (3) Plaintiffs cannot state a claim under MMWA for implied warranty as they failed to plead an express warranty claim; and (4) Plaintiffs failed to provide Defendants with notice and an opportunity to cure prior to initiating this litigation.

Defendants' assertions regarding the Plaintiffs' MMWA claim are meritless.

**a. Plaintiffs' State a Claim for Breach of Implied Warranty.**

Defendants' *ipse dixit* assertion that Plaintiffs have failed to allege sufficient claims for breach of the implied warranty of merchantability and fitness for purpose is addressed above in detail. Plaintiffs have adequately asserted such claims.

**b. Plaintiffs Satisfy the MMWA's Jurisdictional Requirements.**

Defendants' allege that Plaintiffs' have failed to comply with Title 15 U.S.C. § 2310 (d)(3) and the requirement of at least 100 named plaintiffs and at least \$25 in value for each individual claim for class actions. Defendants cite as authority cases that pre-date the 2005 enactment of the Class Action Fairness Act (CAFA), 28 U.S.C. 1332, *et seq.*

Post-CAFA courts have consistently and repeatedly held that, in reconciling CAFA with the MMWA, Plaintiffs need only comply with CAFA's and not also MMWA's jurisdictional requirements in the class action context. *Chavis v. Fidelity Warranty Services* 415 F. Supp 2d 620, 626 (D.S.C. Feb. 13, 2006); *McCalley v. Samsung Electronics Amer. Inc.* 2008 U.S. District LEXIS 28076 (D.N.J. 2008); *Stella v. LVMH Perfumes and Cosmetics*, 564 F. Supp. 2d 833, 837-38 (N.D. Ill. July 8, 2008)(summarizing cases finding CAFA creates an alternative basis for federal jurisdiction and declining to dismiss Magnuson-Moss claim); *In re NVIDIA GPU Litig.*, No. 09-4312, 2009 WL 4020104 at \* 7, n. 5 (N.D. Cal. Nov. 19, 2009)(finding plaintiffs satisfied the MMWA's jurisdictional requirement because they alleged jurisdiction based on CAFA).

CAFA's jurisdictional requirements are located at 28 U.S.C. 1332(d)(2)(A) and require minimum damages of \$5,000,000 (five million dollars) and minimal diversity between the parties. Plaintiffs have pled CAFA jurisdiction in their CAC at ¶ 20, and therefore have successfully pled jurisdiction over an MMWA claim, despite the lack of 100 named plaintiffs or the lack of a specific allegation of \$25 in damages per claim.

**c. Plaintiffs Allege A Breach of Express Warranty.**

Defendants next claim that Plaintiffs may not bring an MMWA implied warranty claim in the absence of an express warranty. This assertion fails because none of the cases the J&J Defendants cite stands for the bright-line rule that a written warranty is a prerequisite to a claim

for breach of an implied warranty under the MMWA. Indeed, at least one of the cases cited by Defendants for such proposition does not even address the issue. *See, e.g., Gross v. Shep Brown's Boat Basin*, No. 99-140, 2000 WL 1480373 at \*1 (D.N.H. Feb. 28, 2000). Further, the MMWA, by its explicit language, authorizes implied warranty claims in the absence of an express warranty. *See* 15 U.S.C. § 2310(d)(1)(imposing liability on any warrantor not just those who offer a written warranty) and 15 U.S.C. § 2301(5) (defining a warrantor as, *inter alia*, anyone who may be obligated under an implied warranty).

In addition, as part of Defendants' argument that a written warranty is a "condition precedent" to bringing an MMWA implied warranty claim, Defendants again rely upon pre-CAFA case law in support. As discussed above, Plaintiffs need only meet the requirements of CAFA to bring an MMWA claim at this juncture. To Plaintiffs' knowledge, no other "condition precedent" has been imposed by any court since the adoption of CAFA.

**d. Plaintiffs Satisfy All Notice Requirements.**

Finally, the Defendants claim that Plaintiffs' MMWA claim fails because Plaintiffs failed to provide notice and an opportunity to cure prior to filing this lawsuit. This argument fails because the Defendants facing the MMWA claim here are remote manufacturers of the Subject Products. Defendants' cited case law actually refutes their contention as to notice. In *Stearns v. Select Comfort Retail Corp.*, No. 07-2746, 2009 WL 163591, (N.D. Cal. June 5, 2009) (J&J Mem. at 43), the court held that, "with regard to a breach of warranty claim, timely notice of breach is not required where the buyers did not purchase the product from the manufacturer directly". *Id.* at 4, n. 3.

Plaintiffs do not allege any direct purchases from any manufacture defendant of any of the Subject Products. Rather, the CAC explicitly details how the J&J Defendants retained the

Contractor Defendants to try to purchase certain Subject Products off the shelves of certain merchants who sold Subject Products to the Plaintiffs. CAC at ¶¶147, 149, 150, and 151.

Further, as discussed above, Plaintiffs have not been required to do anything other than comply with CAFA's requirements to initiate an MMWA class action since the adoption of CAFA. In other words, the Defendants have provided no legal basis for why CAFA would operate to bypass the jurisdictional requirements of 15 U.S.C. § 2310(d), but leave in place the notice/cure language of 15 U.S.C. § 2310(e).

Finally, if the Court is inclined to hold that notice is required under MMWA, the Court should find that any such notice would have been futile. Here, there can be no question that Plaintiffs have alleged that the J&J Defendants knew of the severe defects in their Subject Products and attempted, albeit unsuccessfully, to "cure" the breach with their alleged refund program. The fact that the J&J Defendants had notice and instituted a recall program that did not "cure" the breach should be instructive of whether any further notice from consumers would have been futile. Indeed, the direct interactions of record between consumers and J&J (as evidenced in the limited documents produced by J&J) (*see* CAC Ex. B) reveal that consumer complaints have fallen on deaf ears.

#### **6. Plaintiffs' Have Adequately Pled a Negligence Claim Against Defendants.**

Contractor Defendants challenge Plaintiffs' negligence claim. The facts pled show that Contractor Defendants (1) owed Plaintiffs a duty of care; (2) they breached that duty; and (3) a causal link existed between the breach of duty and Plaintiffs' injury. *See Markovich v. Bell Helicopter Textron*, 805 F.Supp. 1231, 1236 (E.D.Pa. April 6, 1992).

A duty arises when the defendant's conduct exposes the plaintiff to risk of harm. *Miller v. Group Voyager, Inc.*, 912 F.Supp 164, 167 (E.D.Pa. January 26, 1996)(*quoting*

*Alloys, Ltd.*, 772 F.Supp. 244, 253 (W.D.Pa. Aug. 16, 1991)). Foreseeability is the basis on which a duty is established. In other words, the defendant owes the plaintiff a duty if the defendant's actions are “‘*unreasonable*, or expose the plaintiff to an elevated risk of *foreseeable* harm.’” *Id.* (quoting *Brantner v. Black & Decker Mfg. Co.*, 831 F.Supp. 460, 462 (W.D.Pa. Aug. 26, 1993)(quoting *Mohler v. Jeke*, 407 Pa.Super. 478, 595 A.2d 1247, 1252 (1991)).

The Contractor Defendants’ negligent conduct in clandestinely removing select Subject Products from select retail shelves, knowing that all of the products were defective in all of the retail stores, surely exposed the Plaintiffs to risk of foreseeable harm. As is evidenced in the 2009 memorandum, Contractor Defendants knew that J&J Defendants were recalling certain Subject Products when they sought to remove them from some, but not all, retail shelves. *See* CAC Ex. E. In fact, Contractor Defendants instructed their employees to “act like regular customers” while removing the products off shelves, and to make “no mention of [] being a recall.” *Id.* Contractor Defendants created a reasonable and foreseeable risk of harm to Plaintiffs and other consumers who either continued to purchase the Subject Products from retail outlets and/or had such products at their homes already and continued to use them, without knowing they were defective. Contractor Defendants owed Plaintiffs and consumers a duty of care to adequately warn of known defects in the Subject Products, instead of assisting J&J Defendants in performing a “phantom recall,” leaving Plaintiffs and consumers in the dark about harmful medications they themselves were taking or administering to their sick children.

The negligence of Contractor Defendants in facilitating the continued use of defective Subject Products and in suppressing critical information about the defects, is likely to expand as discovery is conducted in this case. A recent internet search (in response to claims by the Contractor Defendants) turned up the letter from Congress to Mr. Weldon, attaching emails

showing the Contractor Defendants were aware of the defects in children's Tylenol, nearly a year before the J&J Defendants issued their recall. *See* Ex. A hereto.

Once Contractor Defendants learned that J&J Defendants' Subject Products were defective, they failed to provide adequate warnings to Plaintiffs and consumers or notify the appropriate government agencies. In failing to take such actions, Contractor Defendants breached their duty of care owed to Plaintiffs and the Class, subjecting them to an unreasonable and foreseeable risk of injury and harm.

Finally, due to the negligence of the Contractor Defendants, Plaintiffs suffered legally cognizable injuries. The affirmative act of conducting limited "phantom recalls", and the deliberate omission of integral information regarding the quality, effectiveness and safety of the Subject Products knowing that such acts and omissions would lead to continued purchase and use of these products, was a direct and proximate cause of Plaintiffs' injuries alleged in this case.

**a. Plaintiffs' Claims Are Not Barred Completely by the  
"Economic Loss Rule."**

Defendants argue that Plaintiffs' negligence claims are barred by the "economic loss rule" because there are no allegations that anyone "suffered physical harm as a result of ingesting any Subject Products." In so arguing, Defendants misstate the "economic loss rule" as disallowing negligence or product liability claims when supported by allegations of purely economic loss and not physical injury. However, the line of California cases Defendants rely upon do not support Defendants' contention that products liability and negligence are only available in personal injury matters.

In *Aas v. Superior Court*, 24 Cal.4<sup>th</sup> 627, 12 P.3d 1125 (Cal.2000), a case concerning construction defects without personal injury, the California Supreme Court explained the economic loss rule as follows: Any construction defect can diminish the value of a house. But



the difference between price paid and value received, and deviations from standards of quality that have not resulted in property damage or personal injury, are primarily the domain of contract and warranty law or the law of fraud, rather than of negligence. In actions for negligence, a manufacturer's liability is limited to damages for physical injuries; no recovery is allowed for economic loss alone. *Aas*, 12 P.3d at 1130-31. However, as the California Supreme Court further explained, a victim can suffer appreciable harm sufficient to bring a claim for products liability or negligence once they have suffered involuntary out of pocket losses: construction defects that have not ripened into property damage, or at least into involuntary out-of-pocket losses, do not comfortably fit the definition of appreciable harm—an essential element of a negligence claim. *Id.* at 1137 (quoting *Davies v. Krasna*, 14 Cal.3d 502, 513(Cal.1975)). Moreover, the California Supreme Court has explained that the economic loss rule cannot be used to preclude a jury determination of whether alleged appreciable harm has in fact occurred. *Jimenez v. Superior Court*, 29 Cal.4th 473, 58 P.3d 450 (Cal.2002); *KB Home v. Superior Court*, 112 Cal.App.4th 1076, 5 Cal. Rptr.3d 587 (Cal.App.2Dist.2003).

In this case, Plaintiffs allege that they have incurred involuntary out-of-pocket expenses as a result of purchasing the defective Subject Products. J&J Defendants themselves strongly admonished Plaintiffs to follow a “smarxt disposal” procedure for disposing of the dangerous product – a procedure that necessarily involves incurring involuntary out-of-pocket expenses. CAC ¶¶12, 13. The procedure requires, among other things, the use of sealable bags as well as kitty litter, saw dust or coffee grounds. Therefore, Plaintiffs were directed by Defendants to incur “appreciable harm” in dealing with the defective products at issue, in the form of involuntary added precautions. These were apart from the failure of the products to meet

expectations. As such, Defendants' citations to the economic loss rule should not stand as a bar to the Plaintiffs' claims for strict liability and negligence at this stage.

**7. Plaintiffs' Claims of Negligent Misrepresentation and Fraud Are Adequately Pled Under the Laws of the Applicable States.**

**a. Plaintiffs Have Adequately Pled Actual Injury Proximately Caused By the Defendants.**

As an initial matter, the J&J Defendants generally assert that Plaintiffs' claims for fraud must be dismissed because they have not been pled with particularity. *See* J&J Mem. at §II.G. However, Subsection 1 of the J&J Defendants' Memo asserts only that Plaintiffs' fraud claims must be dismissed because "Plaintiffs have not alleged actual injury". *See id.* at §II.G.1. The Contractor Defendants alleged the same in §I.A. of their Memo in Support. As the purported lack of actual injury is the sum and substance of Defendants' assertions, Plaintiffs address only such assertions.

Plaintiffs previously demonstrated how they have adequately pled actual injury proximately caused by Defendants' acts and omissions. Because Defendants' arguments here offer nothing new, Plaintiffs simply reference their prior response above.

**b. Plaintiffs' Negligent Misrepresentation Claims Are Adequately Pled Under the Laws of Their Home States.**

The crux of Defendants' argument about the inadequacy of the allegations to support negligent misrepresentation is, again, a misguided claim that no adequate injury has been alleged. The CAC is replete with allegations pertaining to the misrepresentations regarding the quality and condition of the Subject Products in light of known defects. The CAC also contains numerous allegations regarding the nature and extent of the defects within those products. Finally, the CAC alleges that the Plaintiffs purchased the Subject Products believing them to be of the quality and condition they claimed to be. Under all state laws, such a scenario

demonstrates injury to the purchasing public. As was analyzed previously, to show an injury in fact, the plaintiff need only allege an injury that is “concrete and particularized” and actual or imminent. *See Friends of the Earth, Inc.*, 528 U.S. at 180-181.

This case is like the case of *In re Mattel*, 588 F.Supp.2d 1111, 1115-16, (C.D.Cal. Dec. 8, 2008). In *Mattel*, plaintiffs bought some defective products and they should have received a refund. The court observed: “Plaintiffs properly allege damages for the purchase price of the toys that allegedly were defective and not fit for their represented use. Plaintiffs’ claim is straightforward – they allege that they purchased toys that were unsafe and unusable and should get their money back. Defendants’ argument that some Plaintiffs have not been injured because they received replacement toys in the voluntary recalls is unpersuasive. While the replacement program is relevant to the preemption discussion above, unilateral offering of a remedy by a defendant does not change the fact that a plaintiff has been injured. The Court knows of no authority for the proposition that a defendant can defeat a plaintiff’s claim on standing grounds through the unilateral offering of a remedy of the defendant’s choosing.” It is respectfully submitted that this Court should adopt the reasoning of *Mattel* as to Plaintiffs’ state law claims and the remedies offered thereunder.

#### **8. Plaintiffs’ Claims of Conspiracy, Concert of Action and Aiding and Abetting Are Adequately Pled Under the Laws of Their Home States.**

Plaintiffs’ have adequately pled claims regarding conspiracy, aiding and abetting and concert of action. Generally speaking, a cause of action for conspiracy requires at least two people, an agreement to commit a wrongful act, an overt act in furtherance of the agreement, and damages. *See, e.g., Kline v. Sec. Guards, Inc.*, 386 F.3d 246, 262 (3d Cir.2004)(Under Pennsylvania law, a cause of action for conspiracy requires that the plaintiff demonstrate a combination of at least two individuals acting with a common purpose of committing an

unlawful act, an overt act in furtherance of this agreement, and some sort of legal damage to the plaintiff); *Banco Popular N. Am. v. Gandi*, 876 A.2d 253, 263 (N.J. 2005)(Under New Jersey law, a conspiracy requires two or more people acting together, an agreement to commit an act to inflict a wrong, an overt act in furtherance of this agreement, and damages). Aiding and abetting generally requires a plaintiff to show that the party, aided by the defendants, performed a wrongful act that caused an injury, the defendants were aware of his role as part of an illegal or tortuous activity when he provided the assistance, and the defendants knowingly and substantially assisted the principal violation. *See, e.g., Hurley v. Atlantic City Police Dep't.*, 174 F.3d 95, 127 (3d Cir. 1999); *Szelc v. Stanger*, 2011 WL 1467187 at \* 10 (D.N.J. April 18, 2011). Concert of action similarly requires a wrongful act.

Defendants assert that that Plaintiffs' claims "depend on the actual commission of a tort." Defendants are wrong. Plaintiffs' claims require the commission of a wrongful act or a lawful act performed in an unlawful matter. One can conspire to do many things that do not rise to the level of an actionable tort<sup>21</sup>. Further, some jurisdictions recognize conspiracy as an independent

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<sup>21</sup> *See Hernandez v. CIBA-GEIGY Corp. USA*, 2000 WL 33187524 at \*4, n.4 (S.D. Texas Oct. 17, 2000)(Conspiracy to violate fraud and non-fraud based provisions of the New Jersey Consumer Fraud Act and the United Nations Convention on Psychotropic Substances); *Board of Education of the City of Asbury Park v. Hoek*, 183 A.2d 633, 647 (N.J. 1962(sufficient evidence for jury to infer conspiracy to avoid state bidding statute); *Morgan v. Union County Board of Chosen Freeholders*, 633 A.2d 985, 999 (N.J. Super. 1993(finding that sufficient evidence existed for inference of the existence of a conspiracy to violate civil rights and that claim should have gone to the jury); *Estate of Bennett v. Wainwright*, 548 F.3d 155, 178 (1st Cir.2008) ("A civil rights conspiracy as commonly defined is 'a combination of two or more persons acting in concert to commit an unlawful act, or to commit a lawful act by unlawful means, the principal element of which is an agreement between the parties to inflict a wrong against or injury upon another, and an overt act that results in damages.' ") (quoting *Earle v. Benoit*, 850 F.2d 836, 844 (1st Cir.1988)).

tort<sup>22</sup>. For those jurisdictions where something more is required, Plaintiffs cite to their viable claims for consumer fraud, among others, for which the Defendants may be held jointly and severally liable by an “associational” claim of conspiracy, concert of action and/or aiding and abetting.

### **9. Plaintiffs’ Claims for Unjust Enrichment Are Adequately Pled.**

The J&J Defendants correctly characterize the general standard for unjust enrichment as being an allegation by the plaintiff that he or she conferred a benefit on a defendant, and that a defendant’s retention of that benefit without payment would be unjust. The J&J Defendants then claim Plaintiffs’ claim for unjust enrichment fails because every Plaintiff allegedly has been offered “replacement coupons or cash refunds” for every purchase of every Recalled Subject Product. *See* J&J Mem. at 53. (This argument is erroneous for reasons previously discussed).

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<sup>22</sup> The concurring decision of Judge Sloviter of the Third Circuit in *Franklin Music Co. v. American Broadcasting Companies*, 616 F.2d 528 (3d Cir. 1979) traces the history of the development of the claim of civil conspiracy:

Examination of the definition of the tort of civil conspiracy, as usually formulated in Pennsylvania, evidences two separate and independent grounds for liability. One entails a combination to do an unlawful act, unlawful being, in the civil law, that which is tortious. The other entails a combination to do a lawful act by unlawful means. As will be seen, this does not require use of tortious methods but refers to the element of intent. Some inquiry into the historical development of the civil tort of conspiracy is necessary to understand the distinguishing features of each of the distinct strains of the modern tort.

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Although no specific discussion of the issue has been located, it appears that the modern Pennsylvania tort of civil conspiracy is a fusion of both lines of cases and makes actionable the tort of conspiracy under either of the antecedent strains. ... It is necessary to recognize under which aspect of the conspiracy tort the action is proceeding because there are distinct elements and characteristics pertinent to each. A conspiracy which is actionable as a combination to do a tortious act may easily be confused with an action claiming damages for the tortious act itself. In fact, it is questionable whether one should be permitted to recover for both the substantive tort and the conspiracy to engage in the substantive tort. We have found no Pennsylvania case which permits recovery for both, and no discussion of the issue in the Pennsylvania cases.”

*See, e.g., Churrica v. Miami Jai-Alai, Inc.*, 353 So. 2d 547, (Fl. 1978)(holding that an independent cause of action for civil conspiracy existed).

As with conspiracy, the J&J Defendants contend there is some bright line rule requiring maintenance of a separate tort as prerequisite for unjust enrichment. *Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d 912, 936-37 (3d Cir. 1999) is quoted by J&J Defendants in support of their pronouncement that “there is no justification for permitting plaintiffs to proceed on [an] unjust enrichment claim once [the court has]determined that . . . the traditional tort claims” were “properly dismissed,” J&J Mem. at 56. The quotation is taken out of context. The *Steamfitters* court went on to hold that unjust enrichment claims can be made when plaintiffs seek to recover from defendant for a benefit conferred under an unconsummated or void contract. *See Steamfitters Local Union No. 420 Welfare Fund v. Phillip Morris, Inc.*, 171 F.3d at 936.

The J&J Defendants also claim that “a number of states do not permit recovery for unjust enrichment where the plaintiff has not conferred a *direct* benefit on the defendants, or where there is not a *direct* relationship between the parties.” J&J Mem. at 58. Defendants do not accurately cite the law in the States where they claim direct relationships or direct benefits are required. For example, Defendants cite *In re Whirlpool Corp., Front Loading Washer Products Liab, Litig.*, 684 F. Supp. 2d 942, 951-53 (N.D. Ohio Nov. 4, 2009), for some bright line rule that Ohio requires a direct relationship. The J&J Defendants misconstrue the Ohio court’s holding. The *Whirlpool* court did not hold that unjust enrichment could not be maintained because of a lack of direct relationship; instead, the court found that the plaintiff had not conferred an economic benefit to the defendant. *See id.* at 953. Instructively, the *Whirlpool* court cited an earlier Ohio state case, *Johnson v. Microsoft Corp.*, 106 Ohio St. 3d 278, 834 N.E. 2d 791 (Ohio 2005), where the court stated that “an indirect purchaser cannot assert a common law claim for restitution and unjust enrichment against a defendant without establishing that a benefit had been

conferred upon that defendant by the purchaser.” *Id.* at 799 (emphasis added). Consequently, proof of a benefit conferred is required; privity between the parties or directness of the benefit is not required. *See id.*

Instructive on the question “benefit conferred” is the fact that the Johnson & Johnson Defendants are providing refunds of coupons and cash directly to affected consumers. J&J Defendants should be hard-pressed to claim that they did not receive a benefit from the purchases of their defective products when J&J is itself providing benefits back to these purchasers.

#### **10. Plaintiffs’ Request for Declaratory Relief Is Valid.**

28 U.S.C.A. § 2202 specifically provides that “necessary or proper relief based on a declaratory judgment or decree may be granted, after reasonable notice and hearing, against any adverse party whose rights have been determined by such judgment.” Defendants challenge every cause of action Plaintiffs have asserted and cite such attack as the predicate for denying declaratory and other relief.

As an initial matter, Defendants’ assertion that declaratory relief under § 2202 is not a cause of action misconstrues the statute in that a proceeding for declaratory relief does not have to be based upon the commission of some wrongful act. *See U.S. v. Fisher-Otis Co., Inc.* 496 F.2d 1146, 1151 (10<sup>th</sup> Cir. 1974). The standard for ripeness in a request for declaratory judgment is that “there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.” *Maryland Cas. Co. v. Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Indeed, in a declaratory judgment action, no actual wrong need have been committed or loss have occurred in order to sustain the action. *Johnson v. Interstate Transit Lines*, 163 F.2d 125 (10th Cir. 1947).

Plaintiffs allege that the Defendants' conduct directly and proximately caused Plaintiffs and the Class to pay exorbitant prices for the Subject Products over cheaper, more effective and less harmful medications and alternative courses of treatment. The Defendants oppose such claims. The parties therefore have adverse legal interests of sufficient immediacy and reality to warrant the issuance of declaratory relief. *See* 28 U.S.C. 2202.



#### IV. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully asks this Court to deny the Defendants' Motions to Dismiss their Amended Complaint.

Dated: May 13, 2011

Respectfully submitted,

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*Members of Plaintiffs' Steering Committee*

**CERTIFICATE OF SERVICE**

I, Donald E. Haviland, Jr., hereby certify that on May 13, 2011 a true and correct copy of the foregoing Plaintiffs' Omnibus Opposition to Defendants' Motions to Dismiss was served on all counsel of record via CM/ECF.

/s/ Donald E. Haviland, Jr.  
Donald E. Haviland, Jr.